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Federal Register

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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Parts 1 and 2

RIN 0503–AA68

Delegations of Authority

AGENCY: Office of the Secretary, USDA.

ACTION: Final rule.

SUMMARY: This document revises the delegations of authority from the Secretary of Agriculture and general officers of the Department of Agriculture (USDA) to reflect changes and additions to the delegations as summarized below. This rule also amends the scope and applicability of the rules of practice governing formal adjudicatory hearings to include actions initiated under the National Forest Roads and Trails Act.

DATES: Effective July 26, 2022.

FOR FURTHER INFORMATION CONTACT: Melissa McClellan, Office of the General Counsel, (202) 720–5565, *melissa.mcclellan@usda.gov.*

SUPPLEMENTARY INFORMATION:

Overview of Changes

A. Realignment of the Office of Tribal Relations

This rule amends the delegations of authority in 7 CFR part 2 to reflect the realignment of the Office of Tribal Relations (OTR) from a staff office within the Office of Partnerships and Public Engagement (OPPE) to a staff office whose head reports directly to the Secretary of Agriculture (Secretary). *See* Secretary's Memorandum 1077–002 (June 24, 2021), available at *https://www.ocio.usda.gov/document/secretarys-memorandum-1077-002.* The rule relocates the delegations of authority to the Director of OTR from § 2.701 in Subpart V to § 2.39 in Subpart D and removes the delegations of authority to the Director of OPPE related to the Office of Tribal Relations.

B. Realignment of the Office of the Executive Secretariat

This rule amends the delegations of authority in 7 CFR part 2 to reflect the realignment of the Office of the Executive Secretariat (OES). *See* Secretary's Memorandum 1076–06 (Aug. 14, 2020), available at *https://www.ocio.usda.gov/document/secretarys-memorandum-1076-036.* Pursuant to this realignment, the Departmental directives and forms functions previously assigned to the Director of OES have been reassigned to the Director of the Office of Budget and Program Analysis (OBPA). In addition, the Departmental records management functions previously assigned to the Director of OES have been reassigned to the General Counsel. Further, the rule revises the delegations of authority to reflect that the Director of OES and the Secretarial correspondence management function and support for the Immediate Office of the Secretary have been removed from the supervision of the Assistant Secretary for Administration (ASA) and now reside in the Office of the Secretary. To reflect the move of the Director of OES from the Departmental Administration mission area to the Office of the Secretary, this rule redesignates the delegations to the Deputy Secretary at § 2.15 to reserved § 2.14, moves the delegations of authority to the Under Secretary for Trade and Foreign Agricultural Affairs (TFAA) from § 2.26 to § 2.15, and moves the delegations of authority to the Director of OES from § 2.97 to § 2.26. This rule moves § 2.26 to Subpart D, Delegations of Authority to Other General Officers and Agency Heads, and amends the cross-references to the delegations of authority to the Under Secretary for TFAA in §§ 2.22, 2.600, 2.601, and 2.602.

C. Additional Delegations Under the Agriculture Improvement Act of 2018

Section 7611 of the Agriculture Improvement Act of 2018 (''the Act''), Public Law 115–334, renamed the Agriculture Conservation Experienced Services (ACES) program authorized under section 1252 of the Food Security Act of 1985 (16 U.S.C. 3851) the ''Experienced Services Program'' and expanded the authority to cover technical, professional, and administrative services to support the Research, Education, and Economics (REE) mission area of the Department. A previous rule implementing the Act added new delegations for the expanded program authority to the Under Secretary for REE and to the Director of NIFA. *See,* Revision of Delegations of Authority, 85 FR 65500–01 (Oct. 15, 2020). This rule revises the delegations of authority to reflect that the Experienced Services Program authority has been further assigned to the Administrators of the Agricultural Research Service (ARS), the Economic Research Service (ERS), and the National Agricultural Statistics Service (NASS).

Section 8642 of the Act (7 U.S.C. 7655c) established a new authority for the Secretary to carry out activities related to performance-driven research and development, education, and technical assistance for the purpose of facilitating the use of innovative wood products in wood building construction, including the authority to make competitive grants to institutions of higher education. This rule revises the delegations of authority to the Chief of the Forest Service, through the Under Secretary for Natural Resource and Environment (NRE), to include the authority under 7 U.S.C. 7655c, as previously assigned in Secretary's Memorandum 1076–030 (July 1, 2019), available at *https://www.ocio.usda.gov/document/secretarys-memorandum-1076-030.*

D. Service First Initiative

The ''Service First'' initiative, codified at 43 U.S.C. 1703, authorizes the Secretary of Agriculture and the Secretary of the Interior to establish joint projects, co-locate in facilities, and make reciprocal delegations of authority to promote customer service and efficiency. Although initially limited to land management agencies, Congress amended the authority in 2014 to make it available to all bureaus or offices of USDA and the Department of the Interior. This rule extends the Service First authority to the Under Secretary for Farm Production and Conservation (FPAC), following an initial delegation in a Secretary's Memorandum issued January 4, 2021.

E. Miscellaneous Revisions to Part 2

Section 5 of the Department of Agriculture Organic Act of 1956 (7 U.S.C. 2228) authorizes the Department to furnish subsistence to employees

without consideration as, or deduction from, the compensation of such employees where warranted by emergency conditions connected with the work of the Department under regulations prescribed by the Secretary. This rule revises the delegations of authority to the Under Secretary for NRE and the Chief of the Forest Service to confirm that this Departmental authority is available to the Forest Service. Further, this revision to the published delegations confirms the existing authority of the Forest Service to provide subsistence, including quarters and meals, to agency personnel in emergency conditions, such as wildland firefighters, in a manner that takes into account health and safety requirements resulting from the COVID–19 pandemic and other such emergencies.

This rule also modifies the existing delegation of authority from the Under Secretary for NRE to the Chief of the Forest Service at § 2.60 concerning the authority to acquire land under the Weeks Act and special forest receipts acts. The revision streamlines the land acquisition process by removing the exception, for acquisitions of $250,000 in value or greater, to the Chief's delegation of authority to approve such acquisitions and by eliminating the corresponding reservation of authority by the Under Secretary for NRE to approve such land acquisitions.

In addition, this rule makes general updates to the delegations to the Director of the Office of Homeland Security in § 2.95 and the related delegations to the Assistant Secretary for Administration (ASA) in § 2.24(a)(8). The rule moves the delegations to the ASA related to physical security and safety of personnel from 2.24(a)(8) to a new paragraph (a)(11) to reflect that these delegations are further assigned to the Office of Safety, Security, and Protection. This rule also corrects an internal citation in a delegation to the Under Secretary for NRE.

This rule makes revisions throughout Part 2 to reflect the name change of the former Office of Property and Fleet Management to the Office of Environmental Management. *See* Secretary's Memorandum 1077–001 (March 26, 2021), available at *https://www.ocio.usda.gov/document/secretarys-memorandum-1076-037.*

This ruled further amends the existing delegations to the Under Secretary for FPAC and the Administrator of the Farm Service Agency (FSA) under 7 U.S.C. 2204b(b)(4) to enter into cooperative agreements related to outreach and technical assistance for FSA programs, as previously implemented in Secretary's Memorandum 1077–003 (July 26, 2021) available at *https://www.ocio.usda.gov/document/secretarys-memorandum-1077-003.*

F. Addition of National Forest Roads and Trails Act to USDA's Rules of Practice

In addition to the revisions to Part 2, this rule also amends the scope of and applicability of USDA's rules of practice for formal adjudicatory hearings at 7 CFR part 1, subpart H, to include proceedings under the National Forest Roads and Trails Act (FRTA) (16 U.S.C. 534). FRTA requires a formal adjudicatory proceeding for revocation of easements for nonuse, provided the holder requests one within 60 days of receipt of the notice of revocation. Revising 7 CFR 1.131 to add FRTA to the list of statutory provisions does not require public notice and comment as it is a technical, non-discretionary change to comply with statutory law.

Classification

This rule relates to internal agency management. Accordingly, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register**. This rule also is exempt from the provisions of Executive Orders 12866 and 13771. This action is not a rule as defined by the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.,* or the Congressional Review Act, 5 U.S.C. 801 *et seq.,* and thus is exempt from the provisions of those acts. This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

7 CFR Part 1

Administrative practice and procedure, Agriculture, Antitrust, Claims, Cooperatives, Courts, Equal access to justice, Fraud, Freedom of information, Government employees, Lawyers, Motion pictures, Penalties, Privacy.

7 CFR Part 2

Authority delegations (Government agencies).

Accordingly, as discussed in the preamble, 7 CFR Subtitle A is amended as follows:

Subtitle A—Office of the Secretary of Agriculture

PART 1—ADMINISTRATIVE REGULATIONS

Subpart H—Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes

■ 1. The authority citation for subpart H is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 61, 87e, 228, 268, 499o, 608c(14), 1592, 1624(b), 1636b, 1638b, 2151, 2279e, 2621, 2714, 2908, 3812, 4610, 4815, 4910, 6009, 6107, 6207, 6307, 6411, 6519, 6520, 6808, 7107, 7734, 8313; 15 U.S.C. 1828; 16 U.S.C. 534, 620d, 1540(f), 3373; 21 U.S.C. 104, 111, 117, 120, 122, 127, 134e, 134f, 135a, 154, 463(b), 621, 1043; 30 U.S.C. 185(o)(1); 43 U.S.C. 1740; 7 CFR 2.27, 2.35.

7 CFR § 1.131

■ 2. Amend § 1.131(a) by adding a statutory provision to the list in alphabetical order to read as follows:

§ 1.31 Scope and applicability of this subpart.

(a) * * *

National Forest Roads and Trails Act (16 U.S.C. 534).

* * * * *

PART 2—DELEGATIONS OF AUTHORITY BY THE SECRETARY OF AGRICULTURE AND GENERAL OFFICERS OF THE DEPARTMENT

■ 3. The authority citation for part 2 continues to read as follows:

Authority: 7 U.S.C. 6912(a)(1); 5 U.S.C. 301; Reorganization Plan No. 2 of 1953, 3 CFR 1949–1953 Comp., p. 1024.

PART 2—[AMENDED]

■ 4. In part 2, revise all references to ''Director, Office of Property and Fleet Management'' to read ''Director, Office of Property and Environmental Management''.

Subpart C—Delegations of Authority to the Deputy Secretary, Under Secretaries, and Assistant Secretaries

§ 2.15 [Redesignated]

■ 5. Redesignate § 2.15 as § 2.14.

§ 2.26 [Redesignated]

■ 6. Redesignate § 2.26 as § 2.15.

■ 7. Amend the newly redesignated § 2.15 by revising paragraphs (a)(1)(iv) and removing and reserving paragraph (a)(1)(vii)(F) to read as follows:

§ 2.15 Under Secretary for Trade and Foreign Agricultural Affairs.

(a) * * *

(1) * * *

(iv) Conduct functions of the Department relating to WTO, the Trade Expansion Act of 1962 (19 U.S.C. 1801 *et seq.*), the Trade Act of 1974 (19 U.S.C. 2101 *et seq.*), the Trade Agreements Act of 1979 (19 U.S.C. 2501 *et seq.*), the Omnibus Trade and Competition Act of 1988 (19 U.S.C. 2901 *et seq.*), and other legislation affecting international agricultural trade including the programs designed to reduce foreign tariffs and other trade barriers.

* * * * *

■ 8. Amend § 2.16 by revising paragraphs (a)(1)(xxviii)(B) and (a)(12) to read as follows:

§ 2.16 Under Secretary for Farm Production and Conservation.

(a) * * *

(1) * * *

(xxviii) * * *

(B) Administer cooperative agreements with Federal agencies, State, local, and tribal governments, nongovernmental organizations, and educational institutions related to outreach and technical assistance for programs carried out by the Farm Service Agency, and, where such cooperative agreements focus on outreach activities to beginning, underserved, or veteran producers, coordinate with the Director, Office of Partnerships and Public Engagement to reduce potential duplication.

* * * * *

(12) Establish programs with any bureau of the U.S. Department of the Interior (DOI), or with other agencies within USDA, in support of the Service First initiative for the purpose of promoting customer service and efficiency, including delegating to employees of DOI and other USDA agencies the authorities of the agencies in the Farm Production and Conservation mission area necessary to carry out projects on behalf of USDA (43 U.S.C. 1703).

* * * * *

■ 9. Amend § 2.20 by revising the introductory text of paragraph (a)(2)(xxiv)(A) and (a)(2)(lv) and adding paragraph (a)(2)(lvi) to read as follows:

§ 2.20 Under Secretary for Natural Resources and Environment.

(a) * * *

(2) * * *

(xxiv) * * *

(A) Administer the forestry aspects of the programs listed in paragraphs (a)(2)(xxiv)(A)(*1*) through (*3*) of this section on the National Forest System, rangelands with national forest boundaries, adjacent rangelands which are administered under formal agreement, and other forest lands;

* * * * *

(lv) Conduct performance-driven research and development, education, and technical assistance for the purpose of facilitating the use of innovative wood products in wood building construction in the United States (7 U.S.C. 7655c) and administer the Wood Innovation Grant program (7 U.S.C. 7655d).

(lvi) Furnish subsistence to employees without consideration as, or deduction from, the compensation of such employees where warranted by emergency conditions connected with the work of the Forest Service (7 U.S.C. 2228).

* * * * *

§ 2.22 [Amended]

■ 10. In § 2.22, revise all references to ''§ 2.26(a)(1)(x)'' to read ''§ 2.15(a)(1)(x)''.

■ 11. Amend § 2.24 by:

■ a. Revising paragraph (a)(8);

■ b. Removing and reserving paragraphs (a)(9)(iii) and (a)(10); and

■ c. Revising paragraph (a)(11).

The revisions read as follows:

§ 2.24 Assistant Secretary for Administration.

(a) * * *

(8) *Related to homeland security.* (i) Serve as the principal advisor to the Secretary on national security, including emergency management, agriculture and food defense, and foreign investments in U.S. agriculture.

(ii) Coordinate activities of the Department, including policies, processes, budget needs, and oversight relating to national security, including emergency management, biodefense, agriculture and food defense, and foreign investments in U.S. agriculture.

(iii) Act as the primary liaison on behalf of the Department with other Federal departments and agencies in activities relating to national security, including emergency management, integrated laboratory networks, agriculture and food defense, foreign investments in U.S. agriculture, national intelligence collection priorities, and interagency coordination and data sharing.

(iv) Coordinate in the Department the gathering of information relevant to early warning and awareness of threats and risks to the food and agriculture critical infrastructure sector; and share that information with, and provide assistance with interpretation and risk characterization of that information to, the intelligence community (as defined in 5 U.S.C. 3003), law enforcement agencies, the Secretary of Defense, the Secretary of Homeland Security, the Secretary of Health and Human Services, and State fusion centers (as defined in section 210A(j) of the Homeland Security Act of 2002 (6 U.S.C. 124h(j)).

(v) Establish and maintain an effective defensive Counterintelligence Program to counter Foreign Intelligence Entity (FIE) threats to Departmental sensitive information and assets that includes identification and risk assessment to sensitive assets, development and implementation of mitigation strategies, integration of counter-FIE efforts across the Department, sharing of threat information and warnings, and promotion of counterintelligence training awareness.

(vi) Liaise with the Intelligence Community to assist in the development of periodic assessments and intelligence estimates, or other intelligence products, that support the defense of the food and agriculture critical infrastructure sector and risks associated with foreign investments in U.S. agriculture.

(vii) Coordinate the conduct, evaluation, and improvement of exercises to identify and eliminate gaps in preparedness and response.

(viii) Produce a Department-wide centralized strategic coordination plan to provide a high-level perspective of the operations of the Department relating to homeland and national security, including emergency management and agriculture and food defense.

(ix) Establish and carry out an interagency Agriculture and Food Threat Awareness Partnership Program, including by entering into cooperative agreements or contracts with Federal, State, or local authorities (7 U.S.C. 6922).

(x) Administer the Department's Emergency Preparedness Program. This includes:

(A) Coordinate the delegations and assignments made to the Department under the Defense Production Act of 1950, 50 U.S.C. App. 2061, *et seq.;* the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121, *et seq.;* and by Executive Orders 12148, ''Federal Emergency Management'' (3 CFR, 1979 Comp., p. 412), 12656, ''Assignment of Emergency Preparedness Responsibilities'' (3 CFR, 1988 Comp., p. 585), and 13603, ''National Defense Resources Preparedness'' (3 CFR, 2012 Comp., p. 225), or any successor to these Executive Orders, to ensure that the Department has sufficient capabilities to

respond to any occurrence, including natural disaster, military attack, technological emergency, or any all hazards incident.

(B) Manage the Department Emergency Operations Center at Headquarters and the Secretary's alternative facilities; provide senior staff with international, national, and regional situational awareness reports; and provide and maintain current information systems technology and National Security Systems to support USDA executive crisis management capability.

(C) Provide facilities and equipment to facilitate inter-agency coordination during emergencies.

(D) Activate the USDA incident management system in accordance with the National Response Framework and the National Incident Management System in the event of a major incident; and provide oversight and coordination of the Department's Emergency Support Functions as outlined in the National Response Framework.

(E) Develop and promulgate policies for the Department regarding emergency preparedness and national security, including matters relating to anti-terrorism and agriculture-related emergency preparedness planning, both national and international, and guidance to USDA State and County Emergency Boards.

(F) [Reserved]

(G) Provide representation and liaison for the Department in contacts with other Federal entities and organizations, including the National Security Council's functional directorates, Homeland Security Council, Office of Management and Budget, Department of Homeland Security, Federal Emergency Management Agency, Office of the Director of National Intelligence, Department of State, Federal Bureau of Investigation, and Department of Defense concerning matters of a national security, multilateral weapons conventions, natural disasters, other emergencies, and agriculture/food-related international civil emergency planning and related activities.

(H) Act as the primary USDA representative for anti-terrorism activities and coordinates and oversees USDA's agroterrorism defense activities and programs.

(I) [Reserved]

(J) Provide guidance and direction regarding radiological emergency preparedness programs and the implementation of the National Response Framework's Nuclear/Radiological Incident Annex to Departmental staff offices, mission areas, and agencies.

(K) Provide program leadership and coordination for USDA's radiological emergency preparedness requirements with respect to Emergency Management and Assistance (44 CFR parts 350 through 352).

(L) Represent USDA on the Federal Radiological Preparedness Coordinating Committee (FRPCC) and Regional Assistance Committees (RACs) and assist them in carrying out their functions.

(M) Support USDA in its management of the Department's emergency response program with respect to radiological emergency response activities.

(N) [Reserved]

(xi) Administer the Controlled Unclassified Information (CUI) program for the Department pursuant to E.O. 13556, ''Controlled Unclassified Information'' (75 FR 68675, 3 CFR, 2011 Comp., p. 267) and 32 CFR part 2002.

(xii) Serve as the primary point of contact for Government Accountability Office (GAO) and Office of the Inspector General (OIG) audits of USDA homeland and national security activities.

(xiii) Coordinate interaction between Department agencies and private sector businesses and industries in emergency planning and public education under Department authorities delegated or assigned under the National Response Framework, National Infrastructure Protection Plan, Defense Production Act of 1950, 50 U.S.C. App. 2061, *et seq.,* and Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121, *et seq.*

(xiv) Oversee the Department's ability to collect and disseminate information and prepare for an agricultural disease emergency, agroterrorism act, or other threat to agricultural biosecurity, and coordinate such activities among agencies and offices within the Department (7 U.S.C. 8912).

(xv) Promulgate Departmental policies, standards, techniques, and procedures and represent the Department in providing security guidance to the Food and Agricultural Sector nationwide. This includes the following duties:

(A) Provide guidance to USDA agencies and the Food and Agricultural Sector in matters of security through use of assessments and development of mitigation strategies.

(B) Represent and act as liaison for the Department in contacts with other Federal security entities and organizations, including the Interagency Security Committee and the Department of Homeland Security.

(C) Provide guidance and direction to ensure agriculture/food security are fully integrated in USDA's security preparations, which are reported to and coordinated with the White House.

(D) Provide assistance to the USDA agencies in preparation for and during a disaster to identify critical assets and possible alternate storage locations.

(xvi) Provide oversight and coordination of the development and administration of the Department Continuity Program. This includes:

(A) Provide guidance and direction regarding continuity of operations to the Office of the Secretary, Departmental staff offices, mission areas, and agencies.

(B) Represent and act as liaison for the Department in contacts with other Federal entities and organizations concerning matters of assigned continuity program responsibilities.

(C) Oversee Department continuity of operations and emergency relocation facility planning, development, equipping, and preparedness to ensure that resources are in a constant state of readiness.

(xvii) Establish procedures to prevent unnecessary access to classified national security information (CNSI) including procedures that require that need for access to CNSI is established before initiating security clearance procedures; and ensure that the number of persons granted access CNSI is limited to the minimum consistent with operational and security requirements:

(A) Direct and administer USDA's CNSI program pursuant to E.O. 13526, ''Classified National Security Information'' (75 FR 707, 3 CFR, 2010 Comp., p. 298), or subsequent orders.

(B) Establish and maintain Information Security policies and procedures for classifying, declassifying, safeguarding, and disposing of CNSI and materials.

(C) Investigate or delegate authority to investigate any potential compromises of CNSI and take corrective action for violations or infractions under section 5.5(b), of E.O. 13526 or any subsequent order.

(D) Develop and maintain oversight of all facilities throughout USDA where CNSI is or will be safeguarded, discussed, or processed including sole authority to liaison with the Central Intelligence Agency concerning guidance, approval, requirements, and oversight of USDA secure facilities.

(xviii) Control within USDA the acquisition, use, and disposal of material and equipment that can be a source of ionizing radiation.

(A) Promulgate policies and procedures for ensuring the safety of USDA employees, the public, and the environment resulting from USDA's use of ionizing radiation sources.

(B) Maintain and ensure compliance with the Nuclear Regulatory Commission regulations (Title 10, Code of Federal Regulations) and license(s) issued to USDA for the acquisition, use, and disposal of radioactive materials.

(xix) Provide administrative supervision to the unit that grants, denies, or revokes security clearances for USDA employees and contractors.

* * * * *

(11) *Related to safety, security, and protection.* (i) Promulgate Departmental policies, standards, techniques, and procedures; and represent the Department in maintaining the security of physical facilities and providing security guidance to the Food and Agricultural Sector nationwide. This includes the following activities:

(A) Lead and coordinate the development and maintenance of a mission critical facility inventory with agency involvement to ensure proper security countermeasures are implemented in the Department's most critical infrastructure.

(B) Provide guidance to USDA agencies in matters of physical security through use of physical security assessments and development of mitigation strategies.

(C) Conduct physical security investigations and compliance reviews Department-wide.

(D) Review and provide coordinated technical physical security assessments for all new construction of laboratories, data centers, germplasm repositories, and other mission critical infrastructure during the design phase, and all leased facilities prior to contract award.

(E) Oversee and manage physical security aspects of the Common Identification Card (LincPass) Program to ensure National Institute of Standards and Technology (NIST) and General Services Administration (GSA) compliancy within the National Capital Region and the physical access to USDA facilities.

(F) Provide enterprise connectivity to agency physical access control systems that provide cost leveraging and provisioning/de-provisioning nationwide.

(ii) Promulgate Departmental regulations, standards, techniques, and procedures and represent the Department in managing and maintaining a comprehensive physical and technical security program including access control, management of special police officer and guard services, executive driving, parking, ID badging in accordance with HSPD–12, occupant emergency and warden services at the USDA Headquarters Complex, George Washington Carver Center and, in coordination with GSA, USDA leased facilities in the Washington, DC metropolitan area, as well as at emergency relocation sites and certain critical facilities specified by the Assistant Secretary for Administration.

(iii) Carry out protection operations for the Secretary, Deputy Secretary, and other individuals as specified in Section 12520 of the Agriculture Improvement Act of 2018, including by authorizing law enforcement officers or special agents to carry firearms; conduct criminal investigations into potential threats to the security of individuals protected under Section 12520; make arrests without a warrant for any offense against the United States committed in the presence of the law enforcement officer or special agent; perform protective intelligence work, including identifying and mitigating potential threats and conducting advance work to review security matters relating to sites and events; and coordinate with local law enforcement authorities (7 U.S.C. 2279k).

* * * * *

Subpart D—Delegations of Authority to Other General Officers and Agency Heads

■ 12. Add § 2.26 to read as follows:

§ 2.26 Director, Office of the Executive Secretariat.

(a) *Delegations.* The following delegations of authority are made by the Secretary to the Director, Office of the Executive Secretariat:

(1) Exercise responsibility for all correspondence control and related records management functions for the Office of the Secretary;

(2) Provide administrative, editorial, and project management support services to the immediate Office of the Secretary.

(b) [Reserved]

■ 13. Amend § 2.30 by adding paragraph (a)(9) to read as follows:

§ 2.30 Director, Office of Budget and Program Analysis.

(a) * * *

(9) Administer the Departmental forms, reports, and directives management programs.

* * * * *

■ 14. Amend § 2.31 by adding paragraph (d) to read as follows:

§ 2.31 General Counsel.

* * * * *

(d) *Related to records management.* Administer the Departmental records management program.

* * * * *

§ 2.38 [Amended]

■ 15. Amend § 2.38 by removing and reserving paragraph (a)(2).

■ 16. Add § 2.39 to read as follows:

§ 2.39 Director, Office of Tribal Relations.

(a) *Delegations.* The following delegations of authority are made by the Secretary to the Director, Office of Tribal Relations.

(1) Serve as the Department's primary point of contact for tribal issues.

(2) Advise the Secretary on policies related to Indian tribes.

(3) Serve as the official with principal responsibility for the implementation of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' including the provision of Department-wide guidance and oversight regarding tribal consultation, coordination, and collaboration.

(4) Coordinate the Department's programs involving assistance to American Indians and Alaska Natives.

(5) Enter into cooperative agreements to improve the coordination and effectiveness of Federal programs, services, and actions affecting rural areas (7 U.S.C. 2204b(b)(4)); and to provide outreach and technical assistance to socially disadvantaged farmers and ranchers and veteran farmers and ranchers (7 U.S.C. 2279(c)(4)).

(6) Consult with the Administrator, Foreign Agricultural Service on the implementation of section 3312 of the Agriculture Improvement Act of 2018 (7 U.S.C. 5608) to support greater inclusion of Tribal agricultural food products in Federal trade activities.

(7) In coordination with the Under Secretary for Rural Development, provide technical assistance to improve access by Tribal entities to rural development programs funded by the Department of Agriculture through available cooperative agreement authorities (7 U.S.C. 2671).

(8) Oversee the Tribal Advisory Committee (7 U.S.C. 6921).

(b) [Reserved]

Subpart F—Delegations of Authority by the Under Secretary for Farm Production and Conservation.

■ 17. Amend § 2.42 by removing and reserving paragraph (a)(42) and revising paragraph (a)(50)(ii) to read as follows:

§ 2.42 Administrator, Farm Service Agency.

(a) * * *

(50) * * *

(ii) Administer cooperative agreements with Federal agencies, State, local, and tribal governments, nongovernmental organizations, and educational institutions related to outreach and technical assistance for programs carried out by the Farm Service Agency, and, where such cooperative agreements focus on outreach activities to beginning, underserved, or veteran producers, coordinate with the Director, Office of Advocacy and Outreach to reduce potential duplication.

Subpart J—Delegations of Authority by the Under Secretary for Natural Resources and Environment

■ 18. Amend § 2.60 by revising paragraphs (a)(3) and (a)(64), adding paragraph (a)(65), and removing paragraph (b)(6) to read as follows:

§ 2.60 Chief, Forest Service.

(a) * * *

(3) Acquire, dispose, and lease lands and interest in lands as may be authorized for the protection, management, and administration of the National Forest System, including the authority to approve acquisition of land under the Weeks Act of March 1, 1911, as amended, and special forest receipts acts (Pub. L. 337, 74th Cong., 49 Stat. 866, as amended by Pub. L. 310, 78th Cong., 58 Stat. 227; Pub. L. 505, 75th Cong., 52 Stat. 347, as amended by Pub. L. 310, 78th Cong., 58 Stat. 227; Pub. L. 634, 75th Cong., 52 Stat. 699, as amended by Pub. L. 310, 78th Cong., 58 Stat. 227; Pub. L. 748, 75th Cong., 52 Stat. 1205, as amended by Pub. L. 310, 78th Cong., 58 Stat. 227; Pub. L. 427, 76th Cong., 54 Stat. 46; Pub. L. 589, 76th Cong., 54 Stat. 297; Pub. L. 591, 76th Cong., 54 Stat. 299; Pub. L. 637, 76th Cong., 54 Stat. 402; Pub. L. 781, 84th Cong., 70 Stat. 632).

* * * * *

(64) Conduct performance-driven research and development, education, and technical assistance for the purpose of facilitating the use of innovative wood products in wood building construction in the United States (7 U.S.C. 7655c) and administer the Wood Innovation Grant program (7 U.S.C. 7655d).

(65) Furnish subsistence to employees without consideration as, or deduction from, the compensation of such employees where warranted by emergency conditions connected with the work of the Forest Service (7 U.S.C. 2228).

* * * * *

Subpart K—Delegations of Authority by the Under Secretary for Research, Education, and Economics

■ 19. Amend § 2.65 by adding paragraph (a)(10) to read as follows:

§ 2.65 Administrator, Agricultural Research Service.

(a) * * *

(10) Administer an experienced services program to obtain technical, professional, and administrative services to support the research, education, and economics mission area of the Department (16 U.S.C. 3851).

* * * * *

■ 20. Amend § 2.67 by adding paragraph (a)(3) to read as follows:

§ 2.67 Administrator, Economic Research Service.

(a) * * *

(3) Administer an experienced services program to obtain technical, professional, and administrative services to support the research, education, and economics mission area of the Department (16 U.S.C. 3851).

* * * * *

■ 21. Amend § 2.68 by adding paragraph (a)(15) to read as follows:

§ 2.68 Administrator, National Agricultural Statistics Service.

(a) * * *

(15) Administer an experienced services program to obtain technical, professional, and administrative services to support the research, education, and economics mission area of the Department (16 U.S.C. 3851).

* * * * *

Subpart P—Delegations of Authority by the Assistant Secretary for Administration

■ 22. Amend § 2.94 by revising paragraph (a) introductory text to read as follows:

§ 2.94 Chief Security Director, Office of Safety, Security, and Protection.

(a) Delegations from the Assistant Secretary for Administration. Pursuant to § 2.24(a)(11), and with due deference for delegations to other Departmental Administration officials, the following delegations of authority are made by the Assistant Secretary for Administration to the Chief Security Director:

* * * * *

■ 23. Revise § 2.95 to read as follows:

§ 2.95 Executive Director, Office of Homeland Security.

(a) Delegations from the Secretary. Pursuant to 7 U.S.C. 6922, Executive Order (E.O.) 10450, ''Security Requirements for Government Employment,'' 18 FR 2489, 3 CFR, 1953 Comp., p. 72, as amended; E.O. 12968, ''Access to Classified Information,'' 60 FR 40245, 3 CFR, 1995 Comp., p. 391; E.O. 13526, ''Classified National Security Information,'' 75 FR 707, 3 CFR, 2010 Comp., p. 298; E.O. 13587, ''Structural Reforms to Improve the Security of Classified Networks and Responsible Sharing and Safeguarding of Classified Information,'' 76 FR 63811, 3 CFR, 2012 Comp., p. 276, and 5 CFR part 732, and with due deference for delegations to other Departmental Administration officials, the following delegations of authority are made by the Secretary to the Executive Director, Office of Homeland Security, pursuant to the Executive Director's responsibilities as the Departmental National Security Programs Officer and Senior Official for Insider Threat, as designated by the Secretary:

(1) Manage the personnel security functions of the Department for making eligibility determinations for individuals who require initial or continued eligibility (SEAD 6, Continuous Evaluation, or its successor) for access to classified information or eligibility to hold a sensitive position in accordance with Security Executive Agent Directive (SEAD) 4, National Security Adjudicative Guidelines, or its successor; sponsoring access to Sensitive Compartmented Information (SCI); and suspending, denying, or revoking access to national security information (E.O. 12968 ''Access to Classified Information'', as amended), notwithstanding the Secretary's authority to remove an employee for national security reasons as outlined in 5 U.S.C. 7532.

(2) Manage the personnel security functions of the Department's suitability program for individuals holding Public Trust positions (positions designated as Moderate or High Risk) established pursuant to 5 CFR part 731 and E.O. 13488, ''Granting Reciprocity on Excepted Service and Federal Contractor Employee Fitness and Reinvestigating Individuals in Positions of Public Trust'' (74 FR 4111, 3 CFR, 2010 Comp., p. 189), as amended, to make initial or continued suitability determinations.

(3) Manage, coordinate, develop, and promulgate policies and training regarding personnel security, and serve as USDA's personnel security liaison to the Office of Personnel Management (OPM), who serves as the Suitability Executive Agent (SuitEA) and the Office of the Director of National Intelligence

(ODNI), who serves as the Security Executive Agent (SecEA).

(4) Review and develop recommendations on classifying, declassifying, and safeguarding national security information for which the Secretary is responsible as Original Classification Authority.

(5) Establish, direct, and maintain an Insider Threat program to deter, detect, and mitigate insider threats in accordance with the National Insider Threat Policy and Minimum Standards for Executive Branch Insider Threat Programs, November 21, 2012, and subsequent guidance from the National Insider Threat Task Force (NITTF).

(b) Delegations from the Assistant Secretary for Administration. Pursuant to § 2.24(a)(8), and with due deference for delegations to other Departmental Administration officials, the following delegations of authority are made by the Assistant Secretary for Administration to the Executive Director, Office of Homeland Security:

(1) Serve as the principal advisor to the Secretary on national security, including emergency management, agriculture and food defense, and foreign investments in U.S. agriculture.

(2) Coordinate activities of the Department, including policies, processes, budget needs, and oversight relating to national security, including emergency management, biodefense, agriculture and food defense, and foreign investments in U.S. agriculture.

(3) Act as the primary liaison on behalf of the Department with other Federal departments and agencies in activities relating to national security, including emergency management, integrated laboratory networks, agriculture and food defense, foreign investments in U.S. agriculture, national intelligence collection priorities, and interagency coordination and data sharing.

(4) Coordinate in the Department the gathering of information relevant to early warning and awareness of threats and risks to the food and agriculture critical infrastructure sector; and share that information with, and provide assistance with interpretation and risk characterization of that information to, the intelligence community (as defined in 5 U.S.C. 3003), law enforcement agencies, the Secretary of Defense, the Secretary of Homeland Security, the Secretary of Health and Human Services, and State fusion centers (as defined in section 210A(j) of the Homeland Security Act of 2002 (6 U.S.C. 124h(j)).

(5) Establish and maintain an effective defensive Counterintelligence Program to counter Foreign Intelligence Entity (FIE) threats to Departmental sensitive information and assets that includes identification and risk assessment to sensitive assets, development and implementation of mitigation strategies, integration of counter-FIE efforts across the Department, sharing of threat information and warnings, and promotion of counterintelligence training awareness.

(6) Liaise with the Intelligence Community to assist in the development of periodic assessments and intelligence estimates, or other intelligence products, that support the defense of the food and agriculture critical infrastructure sector and risks associated with foreign investments in U.S. agriculture.

(7) Coordinate the conduct, evaluation, and improvement of exercises to identify and eliminate gaps in preparedness and response.

(8) Produce a Department-wide centralized strategic coordination plan to provide a high-level perspective of the operations of the Department relating to homeland and national security, including emergency management and agriculture and food defense.

(9) Establish and carry out an interagency Agriculture and Food Threat Awareness Partnership Program, including by entering into cooperative agreements or contracts with Federal, State, or local authorities (7 U.S.C. 6922).

(10) Administer the Department's Emergency Preparedness Program. This includes:

(i) Coordinate the delegations and assignments made to the Department under the Defense Production Act of 1950, 50 U.S.C. App. 2061, *et seq.*; the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121, *et seq.*; and by Executive Orders 12148, ''Federal Emergency Management'' (3 CFR, 1979 Comp., p. 412), 12656, ''Assignment of Emergency Preparedness Responsibilities'' (3 CFR, 1988 Comp., p. 585), and 13603, ''National Defense Resources Preparedness'' (3 CFR, 2012 Comp., p. 225), or any successor to these Executive Orders, to ensure that the Department has sufficient capabilities to respond to any occurrence, including natural disaster, military attack, technological emergency, or any all hazards incident.

(ii) Manage the Department Emergency Operations Center at Headquarters and the Secretary's alternative facilities; provide senior staff with international, national, and regional situational awareness reports; and provide and maintain current information systems technology and National Security Systems to support USDA executive crisis management capability.

(iii) Provide facilities and equipment to facilitate inter-agency coordination during emergencies.

(iv) Activate the USDA incident management system in accordance with the National Response Framework and the National Incident Management System in the event of a major incident; and provide oversight and coordination of the Department's Emergency Support Functions as outlined in the National Response Framework.

(v) Develop and promulgate policies for the Department regarding emergency preparedness and national security, including matters relating to anti-terrorism and agriculture-related emergency preparedness planning, both national and international, and guidance to USDA State and County Emergency Boards.

(vi) [Reserved]

(vii) Provide representation and liaison for the Department in contacts with other Federal entities and organizations, including the National Security Council's functional directorates, Homeland Security Council, Office of Management and Budget, Department of Homeland Security, Federal Emergency Management Agency, Office of the Director of National Intelligence, Department of State, Federal Bureau of Investigation, and Department of Defense concerning matters of a national security, multilateral weapons conventions, natural disasters, other emergencies, and agriculture/food-related international civil emergency planning and related activities.

(viii) Act as the primary USDA representative for anti-terrorism activities and coordinates and oversees USDA's agroterrorism defense activities and programs.

(ix) [Reserved]

(x) Provide guidance and direction regarding radiological emergency preparedness programs and the implementation of the National Response Framework's Nuclear/Radiological Incident Annex to Departmental staff offices, mission areas, and agencies.

(xi) Provide program leadership and coordination for USDA's radiological emergency preparedness requirements with respect to Emergency Management and Assistance (44 CFR parts 350 through 352).

(xii) Represent USDA on the Federal Radiological Preparedness Coordinating Committee (FRPCC) and Regional Assistance Committees (RACs) and

assist them in carrying out their functions.

(xiii) Support USDA in its management of the Department's emergency response program with respect to radiological emergency response activities.

(xiv) [Reserved]

(11) Administer the Controlled Unclassified Information (CUI) program for the Department pursuant to E.O. 13556, ''Controlled Unclassified Information'' (75 FR 68675, 3 CFR, 2011 Comp., p. 267) and 32 CFR part 2002.

(12) Serve as the primary point of contact for Government Accountability Office (GAO) and Office of the Inspector General (OIG) audits of USDA homeland and national security activities.

(13) Coordinate interaction between Department agencies and private sector businesses and industries in emergency planning and public education under Department authorities delegated or assigned under the National Response Framework, National Infrastructure Protection Plan, Defense Production Act of 1950, 50 U.S.C. App. 2061, *et seq.,* and Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121, *et seq.*

(14) Oversee the Department's ability to collect and disseminate information and prepare for an agricultural disease emergency, agroterrorism act, or other threat to agricultural biosecurity, and coordinate such activities among agencies and offices within the Department (7 U.S.C. 8912).

(15) Promulgate Departmental policies, standards, techniques, and procedures and represent the Department in providing security guidance to the Food and Agricultural Sector nationwide. This includes the following duties:

(i) Provide guidance to USDA agencies and the Food and Agricultural Sector in matters of security through use of assessments and development of mitigation strategies.

(ii) Represent and act as liaison for the Department in contacts with other Federal security entities and organizations, including the Interagency Security Committee and the Department of Homeland Security.

(iii) Provide guidance and direction to ensure agriculture/food security are fully integrated in USDA's security preparations, which are reported to and coordinated with the White House.

(iv) Provide assistance to the USDA agencies in preparation for and during a disaster to identify critical assets and possible alternate storage locations.

(16) Provide oversight and coordination of the development and administration of the Department Continuity Program. This includes:

(i) Provide guidance and direction regarding continuity of operations to the Office of the Secretary, Departmental staff offices, mission areas, and agencies.

(ii) Represent and act as liaison for the Department in contacts with other Federal entities and organizations concerning matters of assigned continuity program responsibilities.

(iii) Oversee Department continuity of operations and emergency relocation facility planning, development, equipping, and preparedness to ensure that resources are in a constant state of readiness.

(17) Establish procedures to prevent unnecessary access to classified national security information (CNSI) including procedures that require that need for access to CNSI is established before initiating security clearance procedures; and ensure that the number of persons granted access CNSI is limited to the minimum consistent with operational and security requirements:

(i) Direct and administer USDA's CNSI program pursuant to E.O. 13526, ''Classified National Security Information'' (75 FR 707, 3 CFR, 2010 Comp., p. 298), or subsequent orders.

(ii) Establish and maintain Information Security policies and procedures for classifying, declassifying, safeguarding, and disposing of CNSI and materials.

(iii) Investigate or delegate authority to investigate any potential compromises of CNSI and take corrective action for violations or infractions under section 5.5(b), of E.O. 13526 or any subsequent order.

(iv) Develop and maintain oversight of all facilities throughout USDA where CNSI is or will be safeguarded, discussed, or processed including sole authority to liaison with the Central Intelligence Agency concerning guidance, approval, requirements, and oversight of USDA secure facilities.

(18) Control within USDA the acquisition, use, and disposal of material and equipment that can be a source of ionizing radiation.

(i) Promulgate policies and procedures for ensuring the safety of USDA employees, the public, and the environment resulting from USDA's use of ionizing radiation sources.

(ii) Maintain and ensure compliance with the Nuclear Regulatory Commission regulations (Title 10, Code of Federal Regulations) and license(s) issued to USDA for the acquisition, use, and disposal of radioactive materials.

§ 2.97 [Removed and Reserved]

■ 24. Remove and reserve § 2.97.

Subpart U—Delegations of Authority by the Under Secretary for Trade and Foreign Agricultural Affairs

■ 25. Revise § 2.600 to read as follows:

§ 2.600 Deputy Under Secretary for Trade and Foreign Agricultural Affairs

Pursuant to § 2.15(a), subject to reservations in § 2.15(b), and subject to policy guidance and direction by the Under Secretary, the following delegation of authority is made to the Deputy Under Secretary for Trade and Foreign Agricultural Affairs, if appointed, to be exercised only during the absence or unavailability of the Under Secretary: Perform all the duties and exercise all the powers which are now or which may hereafter be delegated to the Under Secretary for Trade and Foreign Agricultural Affairs: Provided, that this authority shall be exercised by the respective Deputy Under Secretary in the order in which he or she has taken office as a Deputy Under Secretary.

■ 26. Amend § 2.601 by revising paragraph (a) introductory text and paragraph (a)(2) to read as follows:

§ 2.601 Administrator, Foreign Agricultural Service.

(a) *Delegations.* Pursuant to § 2.15(a)(1) and (3), subject to reservations in § 2.15(b), the following delegations of authority are made by the Under Secretary for Trade and Foreign Agricultural Affairs to the Administrator, Foreign Agricultural Service:

* * * * *

(2) Conduct functions of the Department relating to WTO, the Trade Expansion Act of 1962 (19 U.S.C. 1801 *et seq.*), the Trade Act of 1974 (19 U.S.C. 2101 *et seq.*), the Trade Agreements Act of 1979 (19 U.S.C. 2501 *et seq.*), the Omnibus Trade and Competition Act of 1988 (19 U.S.C. 2901 *et seq.*), and other legislation affecting international agricultural trade including the programs designed to reduce foreign tariffs and other trade barriers.

* * * * *

§ 2.602 [Amended]

■ 27. In § 2.602 amend paragraph (a) introductory text by revising the references to ''§ 2.26(a)(5)'' to read ''§ 2.15(a)(5)'' and ''§ 2.26(b)'' to read ''2.15(b)''.

* * * * *

Subpart V—Delegations of Authority by the Director, Office of Partnerships and Public Engagement

* * * * *

§ 2.701 [Removed and Reserved]

■ 28. Remove and reserve § 2.701.

The Secretary of Agriculture, Thomas J. Vilsack, having reviewed and approved this document, is delegating the authority to electronically sign this document to Janie S. Hipp, the General Counsel, for purposes of publication in the **Federal Register**.

Janie S. Hipp,

General Counsel.

[FR Doc. 2022–15742 Filed 7–25–22; 8:45 am]

BILLING CODE 3410–90–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2022–0105]

RIN 3150–AK84

List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM Flood/Wind Multipurpose Canister Storage System, Certificate of Compliance No. 1032, Amendment No. 8

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the Holtec International HI–STORM Flood/Wind Multipurpose Canister Storage System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 8 to Certificate of Compliance No. 1032. Amendment No. 8 revises the description in the certificate of compliance for the Holtec International HI–STORM Flood/Wind system to clearly indicate that only the portions of the components that contact the pool water need to be made of stainless steel or aluminum. Amendment No. 8 also incorporates other minor editorial corrections.

DATES: This direct final rule is effective October 11, 2022, unless significant adverse comments are received by August 25, 2022. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2022–0105, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: William Allen, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6877; email: *William.Allen@nrc.gov* or Andrew G. Carrera, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–1078; email: *Andrew.Carrera@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0105 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0105. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, 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, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2022–0105 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

This rule is limited to the changes contained in Amendment No. 8 to Certificate of Compliance No. 1032 and does not include other aspects of the Holtec International HI–STORM Flood/Wind Multipurpose Canister Storage System (Holtec International HI–STORM FW) cask design. The NRC is using the ''direct final rule procedure'' to issue this amendment because it represents a limited and routine change to an existing certificate of compliance that is expected to be non-controversial. The NRC has determined that, with the requested changes, adequate protection of public health and safety will continue to be reasonably assured. The amendment to the rule will become effective on October 11, 2022. However, if the NRC receives any significant adverse comments on this direct final rule by August 25, 2022, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule, certificate of compliance, or technical specifications.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on March 28, 2011 (76 FR 17019), that approved the Holtec International HI–STORM FW System design and added it to the list of NRC-approved cask designs in § 72.214, ''List of approved spent fuel storage casks,'' as Certificate of Compliance No. 1032.

IV. Discussion of Changes

On July 30, 2021, Holtec International (the applicant) submitted an application to amend the HI–STORM FW System. The amendment includes the following changes:

- Update the HI–STORM FW System description in the certificate of compliance to clearly indicate that only the portions of the components that contact the pool water need to be made of stainless steel or aluminum; and
- Incorporate other minor editorial corrections.

As documented in the preliminary safety evaluation report, the NRC performed a safety review of the proposed certificate of compliance amendment request. The NRC determined that this amendment does not reflect a significant change in design or fabrication of the cask. Specifically, the NRC determined that the design of the cask would continue to maintain confinement, shielding, and criticality control in the event of each evaluated accident condition. In addition, any resulting occupational exposure or offsite dose rates from the implementation of Amendment No. 8 would remain well within the limits specified by 10 CFR part 20, ''Standards for Protection Against Radiation.'' Therefore, the NRC found there will be no significant change in the types or amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents.

The NRC determined that the amended Holtec International HI–STORM FW System cask design, when used under the conditions specified in the certificate of compliance, the technical specifications, and the NRC's regulations, will meet the requirements of 10 CFR part 72; therefore, adequate protection of public health and safety will continue to be reasonably assured. When this direct final rule becomes effective, persons who hold a general license under § 72.210 may, consistent with the license conditions under § 72.212, load spent nuclear fuel into Holtec International HI–STORM FW System casks that meet the criteria of Amendment No. 8 to Certificate of Compliance No. 1032.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC revises the Holtec International HI–STORM FW System cask design listed in § 72.214. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VI. Agreement State Compatibility

Under the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017, and published in the **Federal Register** on October 18, 2017 (82 FR 48535), this rule is classified as Compatibility Category NRC—Areas of Exclusive NRC Regulatory Authority. The NRC program elements in this category are those that relate directly to areas of regulation

reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR chapter I. Therefore, compatibility is not required for program elements in this category. Although an Agreement State may not adopt program elements reserved to the NRC, and the Category ''NRC'' does not confer regulatory authority on the State, the State may wish to inform its licensees of certain requirements by means consistent with the particular State's administrative procedure laws.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC wrote this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

VIII. Environmental Assessment and Finding of No Significant Impact

Under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC has determined that this direct final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has made a finding of no significant impact on the basis of this environmental assessment.

A. The Action

The action is to amend § 72.214 to revise the Holtec International HI–STORM FW System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 8 to Certificate of Compliance No. 1032.

B. The Need for the Action

This direct final rule amends the certificate of compliance for the Holtec International HI–STORM FW System within the list of approved spent fuel storage casks to allow power reactor licensees to store spent fuel at reactor sites in casks with the approved modifications under a general license. Specifically, Amendment No. 8 revises the certificate of compliance as described in Section IV, ''Discussion of Changes,'' of this document, for the use of the Holtec International HI–STORM FW System.

C. Environmental Impacts of the Action

On July 18,1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was analyzed in the environmental assessment for the 1990 final rule. The environmental assessment for this Amendment No. 8 tiers off of the environmental assessment for the July 18, 1990, final rule. Tiering off past environmental assessments is a standard process under the National Environmental Policy Act of 1969, as amended.

The Holtec International HI–STORM FW System is designed to mitigate the effects of design basis accidents that could occur during storage. Design basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an independent spent fuel storage installation, the type of facility at which a holder of a power reactor operating license would store spent fuel in casks in accordance with 10 CFR part 72, can include tornado winds and tornado-generated missiles, a design basis earthquake, a design basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

This amendment does not reflect a significant change in design or fabrication of the cask. Because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of Amendment No. 8 would remain well within the 10 CFR part 20 limits. The NRC has also determined that the design of the cask as modified by this rule would still maintain confinement, shielding, and criticality control in the event of an accident. Therefore, the proposed changes will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. There will be no significant change in the types or the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposures, and no significant increase in the potential for, or consequences from, radiological accidents. The NRC documented its safety findings in the preliminary safety evaluation report.

D. Alternative to the Action

The alternative to this action is to deny approval of Amendment No. 8 and not issue the direct final rule. Consequently, any 10 CFR part 72 general licensee that seeks to load spent nuclear fuel into the Holtec International HI–STORM FW System in accordance with the changes described in proposed Amendment No. 8 would have to request an exemption from the requirements of §§ 72.212 and 72.214. Under this alternative, interested licensees would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee. The environmental impacts would be the same as the proposed action.

E. Alternative Use of Resources

Approval of Amendment No. 8 to Certificate of Compliance No. 1032 would result in no irreversible commitment of resources.

F. Agencies and Persons Contacted

No agencies or persons outside the NRC were contacted in connection with the preparation of this environmental assessment.

G. Finding of No Significant Impact

The environmental impacts of the action have been reviewed under the requirements in the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' Based on the foregoing environmental assessment, the NRC concludes that this direct final rule, ''List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM Flood/Wind Multipurpose Canister Storage System, Certificate of Compliance No. 1032, Amendment No. 8,'' will not have a significant effect on the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

IX. Paperwork Reduction Act Statement

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and Holtec International. These entities do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

XI. Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if (1) it notifies the NRC in advance; (2) the spent fuel is stored under the conditions specified in the cask's certificate of compliance; and (3) the conditions of the general license are met. A list of NRC-approved cask designs is contained in § 72.214. On March 28, 2011 (76 FR 17019), the NRC issued an amendment to 10 CFR part 72 that approved the Holtec International HI–STORM FW System design by adding it to the list of NRC-approved cask designs in § 72.214. On July 30, 2021, Holtec International submitted a request to amend the Holtec International HI–STORM FW System as described in Section IV, ''Discussion of Changes,'' of this document.

The alternative to this action is to withhold approval of Amendment No. 8 and to require any 10 CFR part 72 general licensee seeking to load spent nuclear fuel into Holtec International HI–STORM FW System under the changes described in Amendment No. 8 to request an exemption from the requirements of §§ 72.212 and 72.214. Under this alternative, each interested 10 CFR part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

Approval of this direct final rule is consistent with previous NRC actions. Further, as documented in the preliminary safety evaluation report and environmental assessment, this direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of this direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory; therefore, this action is recommended.

XII. Backfitting and Issue Finality

The NRC has determined that the backfit rule (§ 72.62) does not apply to this direct final rule. Therefore, a backfit analysis is not required. This direct final rule revises Certificate of Compliance No. 1032 for the Holtec International HI–STORM FW System, as currently listed in § 72.214. The revision consists of the changes in Amendment No. 8 previously described, as set forth in the revised certificate of compliance and technical specifications.

Amendment No. 8 to Certificate of Compliance No. 1032 for the Holtec International HI–STORM FW System was initiated by Holtec International and was not submitted in response to new NRC requirements, or an NRC request for amendment. Amendment No. 8 applies only to new casks fabricated and used under Amendment No. 8. These changes do not affect existing users of the Holtec International HI–STORM FW System, and the current Amendment No. 5 continues to be effective for existing users. Amendment Nos. 6 and 7 to Certificate of Compliance No. 1032 have not been issued. While current users of this storage system may comply with the new requirements in Amendment No. 8, this would be a voluntary decision on the part of current users.

For these reasons, Amendment No. 8 to Certificate of Compliance No. 1032 does not constitute backfitting under § 72.62 or § 50.109(a)(1), or otherwise represent an inconsistency with the issue finality provisions applicable to combined licenses in 10 CFR part 52. Accordingly, the NRC has not prepared a backfit analysis for this rulemaking.

XIII. Congressional Review Act

This direct final rule is not a rule as defined in the Congressional Review Act.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons, as indicated.

Document	ADAMS accession No./ **Federal Register** citation
Direct Final Rule, 10 CFR Part 72, ''List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM Flood/Wind System, Certificate of Compliance No. 1032; [NRC–2011–0007] RIN 3150–AI90, March 28, 2011.	76 FR 17019.
Application from Holtec International for Certificate of Compliance No. 1032, Amendment No. 8, to HI–STORM FW System, July 30, 2021.	ML21211A608 (package).
User Need Memorandum Package to J. Shepherd from Y. Diaz-Sanabria with Proposed Certificate of Compliance No. 1032, Amendment No. 8; Associated Proposed Technical Specifications; Appendices A and B; and the Preliminary Safety Evaluation Report, April 6, 2022.	ML22019A111 (package).

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2022–0105. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2022–0105); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy

Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, revise Certificate of Compliance No. 1032 to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1032.

Initial Certificate Effective Date: June 13, 2011, superseded by Amendment Number 0, Revision 1, on April 25, 2016.

Amendment Number 0, Revision 1, Effective Date: April 25, 2016.

Amendment Number 1 Effective Date: December 17, 2014, superseded by Amendment Number 1, Revision 1, on June 2, 2015.

Amendment Number 1, Revision 1, Effective Date: June 2, 2015.

Amendment Number 2 Effective Date: November 7, 2016.

Amendment Number 3 Effective Date: September 11, 2017.

Amendment Number 4 Effective Date: July 14, 2020.

Amendment Number 5 Effective Date: July 27, 2020.

Amendment Number 6 [Reserved]

Amendment Number 7 [Reserved]

Amendment Number 8 Effective Date: October 11, 2022.

SAR Submitted by: Holtec International.

SAR Title: Final Safety Analysis Report for the HI–STORM FW System.

Docket Number: 72–1032.

Certificate Expiration Date: June 12, 2031.

Model Number: HI–STORM FW MPC–37, MPC–89.

* * * * *

Dated: July 13, 2022.

For the Nuclear Regulatory Commission.

Daniel H. Dorman,

Executive Director for Operations.

[FR Doc. 2022–15939 Filed 7–25–22; 8:45 am]

BILLING CODE 7590–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

EPA–R07–OAR–2022–0382; FRL–9767–02–R7]

Air Plan Approval; Missouri; Removal of Control of Emissions From Bakery Ovens

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the State Implementation Plan (SIP) for the State of Missouri. This final action will amend the SIP to remove a rule related to control of emissions from bakery ovens in St. Louis City and Jefferson, St. Charles, Franklin, and St. Louis Counties. The EPA's approval of this rule revision is in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on August 25, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2022–0382. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* 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. Publicly available docket materials are available through *https://www.regulations.gov* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT: William Stone, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7714; email address: *stone.william@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' refer to EPA.

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V. Statutory and Executive Order Reviews

I. What is being addressed in this document?

The EPA is approving the removal of 10 Code of State Regulation (CSR) 10–5.440, *Control of Emissions From Bakery Ovens,* from the Missouri SIP. As explained in detail in the EPA's proposed rule, Missouri has demonstrated that removal of 10 CSR 10–5.440 will not interfere with attainment of the NAAQS, reasonable further progress, or any other applicable requirement of the CAA because the rule applied to a single source that has permanently ceased operations and it therefore no longer serves to reduce emissions in the St. Louis Area (87 FR 27048, May 6, 2022). The public comment period on the EPA's proposed rule opened May 6, 2022, the date of its publication in the **Federal Register** and closed on June 6, 2022. During this period, the EPA received no comments. Therefore, the EPA is finalizing its proposal to remove 10 CSR 10–5.440 from the Missouri SIP.

II. Have the requirements for approval of a SIP revision been met?

The State's submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision from May 15, 2018 to August 2, 2018 and received 11 comments from the EPA. Missouri's July 11, 2019 letter addressed the EPA's comments. The SIP revision meets the substantive SIP requirements of the Clean Air Act (CAA), including section 110 and implementing regulations.

III. What action is the EPA taking?

The EPA is taking final action to approve Missouri's request to remove 10 CSR 10–5.440 from the SIP.

IV. Incorporation by Reference

In this document, the EPA is deleting rules which were previously incorporated by reference from the applicable Missouri SIP. In accordance with requirements of 1 CFR 51.5, the EPA is deleting certain Missouri rules as described in Section I. of this preamble. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov*

and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the 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 CAA. Accordingly, this 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 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 the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; 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 the 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).
- This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).
- Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 26, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Volatile organic compounds.

Dated: July 18, 2022.

Meghan A. McCollister,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart AA—Missouri

§ 52.1320 [Amended]

■ 2. In § 52.1320, the table in paragraph (c) is amended by removing the entry ''10–5.440'' under the heading ''Chapter 5—Air Quality Standards and Air Pollution Control Regulations for the St. Louis Metropolitan''.

[FR Doc. 2022–15745 Filed 7–25–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 171

[EPA–HQ–OPP–2021–0831; FRL–9134.1–03–OCSPP]

RIN 2070–AL01

Notification of Submission to the Secretary of Agriculture; Pesticides; Certification of Pesticide Applicators; Further Extension to Expiration Date of Certification Plans; Draft Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of submission to the Secretary of Agriculture.

SUMMARY: This document notifies the public as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that EPA has forwarded to the United States Department of Agriculture (USDA) a draft final regulatory document concerning ''Pesticides; Certification of Pesticide Applicators; Further Extension to Expiration Date of Certification Plans'' (RIN 2070–AL01). The draft regulatory document is not available to the public until after it has been signed and made available by EPA.

DATES: See Unit I. under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0831, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP 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 and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.* The docket contains historical information and this **Federal Register** document; it does not contain the draft final rule.

FOR FURTHER INFORMATION CONTACT: Carolyn Schroeder, Pesticide Re-Evaluation Division (Mailcode 7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–2376; email address: *schroeder.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is EPA taking?

FIFRA section 25(a)(2)(B) requires the EPA Administrator to provide the Secretary of USDA with a copy of any draft final rule at least 30 days before signing it in final form for publication in the **Federal Register**. The draft final rule is not available to the public until after it has been signed by EPA. If the Secretary of USDA comments in writing regarding the draft final rule within 15 days after receiving it, the EPA Administrator shall include the comments of the Secretary of USDA, if requested by the Secretary of USDA, and the EPA Administrator's response to those comments with the final rule that publishes in the **Federal Register**. If the Secretary of USDA does not comment in writing within 15 days after receiving the draft final rule, the EPA Administrator may sign the final rule for publication in the **Federal Register** any time after the 15-day period.

II. Do any statutory and executive order reviews apply to this notification?

No. This document is merely a notification of submission to USDA. As such, none of the regulatory assessment requirements apply to this document.

List of Subjects in Part 171

Environmental protection, Agricultural worker safety, Applicator competency, Certified applicator, Pesticide safety training, Pesticide worker safety, Pesticides and pests, Restricted use pesticides.

Dated: July 20, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–16008 Filed 7–25–22; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Part 102–173

[FMR Case 2021–02; Docket No. GSA–FMR–2021–0022; Sequence 01]

RIN 3090–AK52

Federal Management Regulation (FMR); Internet GOV Domain

AGENCY: Office of Information Integrity and Access, Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: This final rule adopts without changes the interim rule published January 10, 2022, which implemented provisions of the DOTGOV Online Trust in Government Act of 2020 (''DOTGOV'') applicable to GSA that transfer ownership, management and operation of the DotGov Domain Program from the General Services Administration (GSA) to the Department of Homeland Security (DHS) Cybersecurity and Infrastructure Security Agency (CISA). In the interim rule, GSA removed provisions to the existing jurisdiction of the DotGov domain program that had been delegated to the General Services Administration in 1997.

DATES:

Effective: July 26, 2022.

Applicability Date: As of July 26, 2022, this final rule applies to all newly issued, already in operation, and/or renewed domains.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Marina Fox, Office of Government-wide Policy, Office of Information, Integrity, and Access, at 202–253–6448, or by email at *marina.fox@gsa.gov.* For information pertaining to the status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FMR Case 2021–02.

SUPPLEMENTARY INFORMATION:

I. Background

For more than 20 years, GSA supported government organizations and worked to make the DotGov domain a trusted space. The DotGov domain exists so that the online services of bona fide U.S.-based government organizations are easy to identify on the internet. Increasing the use of the DotGov domain helps the public know where to find official government information. DotGov is critical infrastructure: it is central to the availability and integrity of thousands of online services relied upon by millions of users. Since the DotGov domain underpins communication with and within these institutions, cybersecurity significance of all aspects of DotGov's administration has been increasing rapidly. To provide additional cybersecurity support and expand DotGov domain usage among public entities, the DOTGOV was introduced in the U.S. Senate on October 30, 2019, directing GSA to transfer the DotGov program to CISA.

On December 27, 2020, the DOTGOV was signed into law and enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260). The Act transfers the DotGov internet domain program, as operated by the General Services Administration under title 41, Code of Federal Regulations, to DHS CISA. The Act also orders that on the date CISA begins operational administration of the DotGov internet domain program, the GSA Administrator shall rescind the requirements in part 102–173 of title 41, Code of Federal Regulations applicable to any Federal, State, local, or territorial government entity, or other publicly controlled entity, including any Tribal government recognized by the Federal Government or a State government that is registering or operating a DotGov internet domain. Finally, the DOTGOV orders that in place of the requirements in part 102–173 of title 41, Code of Federal Regulations, CISA, in consultation with the Director of Management and Budget (OMB), shall establish and publish a new set of requirements for the registration and operation of DotGov domains.

On April 26, 2021, GSA transferred ownership, management and operation of DotGov Domain Program to the Department of Homeland Security (DHS), CISA, and CISA published new DotGov domain issuance guidance for government entities in place of the existing INTERNET GOV DOMAIN requirements in part 102–173 of title 41, Code of Federal Regulations.

Beginning on January 10, 2022, GSA sought public comments on these actions for a period of 60 days through publication of an interim rule in the **Federal Register** (FMR Case 2021–02) at 87 FR 1080. GSA received one general comment, which was in support of the FMR Case 2021–02.

This final rule removes provisions to the existing jurisdiction of the DotGov domain that had been delegated to GSA in 1997 and implements provisions of the DOTGOV applicable to GSA that transfer ownership, management and operation of the DotGov domain program from the GSA to DHS CISA.

DotGov Program History

The DotGov program was created in 1997, and GSA OGP became the designated authority for the top level Domain ''DOT GOV'' registry and registrar and the subdomain registrar for FED.US by a delegation of the National Science Foundation through consensus of the Federal Networking Council and Department of Commerce on October 1, 1997. To provide additional support, GSA entered into an agreement with the Department of the Interior's Bureau of Indian Affairs to facilitate the registration of Native Sovereign Nations (NSNs) in the DotGov domain. In 2003, GSA began using the Intergovernmental Cooperation Act (IGCA) as the authority to provide services to U.S. state and

local governments, and began issuing DotGov domains to state and local government entities.

Under GSA's DotGov program management and operations, domain registrations were approved based on established criteria, detailed in Federal Networking Council request for comments (RFC) 2146, May 1997 and in the Code of Federal Regulations—41 CFR part 102–173. GSA's management of the DotGov program also included DotGov DNS Security (DNSSEC), which gives DNS queries origin authenticity and data integrity. This was accomplished by the inclusion of public keys and the use of digital signatures to DNS information. DNSSEC was deployed on the top level Gov domain root zone in January 2008 in accordance with OMB Memorandum M–08–23.

II. Discussion of the Final Rule

A. Summary of Significant Changes

No significant changes.

B. Analysis of Public Comments

The interim rule was published in the **Federal Register** on January 10, 2022 at 87 FR 1080. One comment was received and was in support of the interim rule.

C. Expected Cost Impact to the Public

There is no expected cost to the public from this rule.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

III. Congressional Review Act

This rule is not a major rule under 5 U.S.C. 804(2). Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (codified at 5 U.S.C. 801–808), also known as the Congressional Review Act or CRA, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. GSA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States.

IV. Regulatory Flexibility Act

This final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because it applies to agency management or personnel. Therefore, an Initial Regulatory Flexibility Analysis has not been performed.

V. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FMR do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

List of Subjects in 41 CFR Part 102–173

Government property management internet Gov Domain.

Robin Carnahan,

Administrator.

PART 102–173—[REMOVED]

■ For the reasons set forth in the preamble, and under the authority of the DOTGOV Online Trust in Government Act of 2020 (Title IX, Division U, H.R. 133, Consolidated Appropriations Act, 2021), GSA adopts the interim rule removing 41 CFR part 102–173, which published at 87 FR 1080 on January 10, 2022, as final without changes.

[FR Doc. 2022–15670 Filed 7–25–22; 8:45 am]

BILLING CODE 6820–14–P

Proposed Rules

Federal Register
Vol. 87, No. 142
Tuesday, July 26, 2022

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[Docket No. PRM–50–122; NRC–2020–0150]

Accident Source Term Methodologies and Corresponding Release Fractions

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking dated May 31, 2020, submitted by Brian Magnuson. The petitioner requested that the NRC revise its regulations to codify the source term methodologies and corresponding release fractions recommended in a report issued by Sandia National Laboratories; to codify a modified version of draft regulatory guide DG–1199, including the source term methodologies recommended in the report and the corresponding release fractions; and to account for high burnup fuel pellet fragmentation, relocation, and dispersal outside of the fuel rod during postulated design basis accidents. The NRC docketed the petition on June 18, 2020, and assigned it Docket No. PRM–50–122. The NRC is denying the petition because the proposed changes would unnecessarily reduce the intended flexibility in the NRC's regulatory approach, and they are not necessary to provide reasonable assurance of adequate protection of public health and safety.

DATES: The docket for PRM–50–122 is closed on July 26, 2022.

ADDRESSES: Please refer to Docket ID NRC–2020–0150 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0150. Address questions about NRC Docket IDs to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, 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 sending an email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the Availability of Documents section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–4154737, between 8 a.m. and 4 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Adakou Foli, Office of Nuclear Reactor Regulation; telephone: 301–415–1984; email: *Adakou.Foli@nrc.gov,* or Solomon Sahle, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–3781; email: *Solomon.Sahle@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents:

I. The Petition
II. Public Comments on the Petition
III. Reasons for Denial
IV. Availability of Documents
V. Conclusion

I. The Petition

Section 2.802 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Petition for rulemaking—requirements for filing,'' provides an opportunity for any interested person to petition the Commission to issue, amend, or rescind any regulation. On May 31, 2020, the NRC received a petition for rulemaking (PRM) from Brian Magnuson. The petitioner requested that the NRC amend its regulations in § 50.67, ''Accident source term,'' to codify the following:

- the source term methodologies recommended in the Sandia National Laboratories report SAND2008–6601, ''Analysis of Main Steam Isolation Valve Leakage in Design Basis Accidents Using MELCOR 1.8.6 and RADTRAD,'' issued October 2008; and
- a modified version of draft regulatory guide (DG) DG–1199, ''Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors,'' issued October 2009, that would include the source term methodologies recommended in SAND2008–6601 and the corresponding release fractions.

The petition also requested that the NRC revise § 50.67 to account for high burnup fuel pellet fragmentation, relocation, and dispersal outside of the fuel rod during postulated design-basis accidents.

The DG–1199 was a proposed revision to Regulatory Guide (RG) 1.183, ''Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors,'' Revision 0, issued July 2000, and was not finalized as an update to RG 1.183. After the issuance of DG–1199 for public comment, the staff received a number of public comments and spent significant efforts in addressing the comments, including resolving different NRC staff views on the approach in addressing certain comments. The efforts included soliciting an independent review of certain aspects of the DG–1199 performed by Sandia National Laboratories. In 2017, the NRC received the final responses from Sandia National Laboratories associated with their independent review.

In late 2020, the NRC resumed RG 1.183 revision efforts after considering a significant amount of insight gained since the initial issuance of the DG–1199, including the 2017 Sandia National Laboratories responses and research pertaining to state-of-the-art source term knowledge, such as the fuel fragmentation, relocation, and dispersal. The planned revision will include this information and also will update RG 1.183 to support accident tolerant fuel

and higher enrichment and burnup levels.

The petition identified concerns with the NRC guidance used to calculate radiological doses to comply with the regulations in § 50.67, stating that (1) the current NRC guidance in RG 1.183 is ''conceptually inaccurate'' and ''nonconservative'' based on SAND2008–6601, and (2) nuclear power plants use varying regulatory guidance (*e.g.,* Technical Information Document (TID)-14844, ''Calculation of Distance Factors for Power and Test Reactor Sites,'' issued March 1962; NUREG–1465, ''Accident Source Terms for Light-Water Nuclear Power Plants,'' issued February 1995; and RG 1.183) that relies on different source term methodologies and corresponding release fractions to satisfy the same regulations. The petition argued that due to these concerns, many nuclear power plants are ''likely not in compliance with some, or all of their applicable regulations and requirements, which ultimately protect people and the environment.'' The petitioner stated that the proposed revision to § 50.67 would eliminate inconsistences resulting from the use of different source term methodologies and release fractions and would provide the requisite means to ensure compliance with the underlying regulations.

II. Public Comments on the Petition

On August 24, 2020 (85 FR 52058), the NRC published a notice of docketing of PRM–50–122 and a request for public comment on the PRM in the **Federal Register**. The public comment period closed on November 9, 2020. The NRC received two comment submissions: (1) one commenter (the petitioner) provided supplemental information in support of the petition, and (2) one commenter (an NRC staff member acting in his personal capacity) opposed the petition. This latter comment was withdrawn from the petition docket because it included non-public information. The NRC reviewed the comments in making its decision on the petition.

A summary of the comment from the petitioner and the NRC's response follows. The comment is available as indicated in the Availability of Documents section of this document.

Comment: The petitioner provided additional concerns related to RG 1.183, Revision 0, such as the treatment of uncertainties in the source terms and the behavior of main steam isolation valve leakage. He stated that such issues provide additional justification for codifying a modified version of DG–1199 in § 50.67.

NRC Response: As discussed in more detail in the Reasons for Denial section of this document, the NRC disagrees with the comment, and finds that RG 1.183, Revision 0 continues to provide an acceptable method to address design-basis accident radiological consequences to comply with the applicable regulations. With regard to the continued acceptability of RG 1.183, Revision 0, additional information also appears in the Differing Professional Opinion case file DPO–2020–002, available as indicated in the Availability of Documents section of this document.

III. Reasons for Denial

The NRC is denying the petition because the requested changes would unnecessarily reduce the intended flexibility inherent in § 50.67 and the NRC's overall regulatory approach in the area of design-basis accident radiological consequence analyses. The NRC's current regulations and oversight activities continue to provide reasonable assurance of adequate protection of public health and safety.

Codifying a specific source term methodology and corresponding release fractions in § 50.67 would unnecessarily limit options for meeting the requirements, whereas § 50.67 currently allows the use of alternative sufficient methods of compliance. A detailed approach for determining source term is provided in RG 1.183, Revision 0, which describes one way to meet the requirements in § 50.67.

In § 50.67, the NRC provides requirements on the acceptable dose criteria from the design-basis analyses based upon a major accident assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products (see § 50.67; see also TID–14844 and NUREG–1465). The regulatory approach of using design-basis accidents and applying performance-based regulatory requirements is consistent with the approach provided in other NRC regulations, including § 50.46, ''Acceptance criteria for emergency core cooling systems for lightwater nuclear power reactors,'' and § 50.65, ''Requirements for monitoring the effectiveness of maintenance at nuclear power plants.'' Furthermore, when § 50.67 was promulgated, the NRC did not include a defined methodology for demonstrating compliance, consistent with other regulations related to radiological reactor siting criteria, such as § 100.11, ''Determination of exclusion area, low population zone, and population center distance,'' and § 50.34, ''Contents of applications; technical information.'' Instead, § 50.67 allows changes to the defined source term or the development of other technically sound source term values without requiring additional rulemaking, and the NRC still finds this approach to be appropriate. Therefore, instead of codifying a particular source term methodology, the NRC used NUREG–1465 and other technical information to develop RG 1.183 to provide one acceptable methodology for complying with § 50.67, but not the only one. This has provided the NRC and the nuclear industry with both regulatory clarity and the flexibility to consider and incorporate new research and technical advancements while continuing to ensure safety. The approach in § 50.67 is to provide flexibility in applying basic principles to new situations and the use of evolving methods of analyses in the licensing process, and not to include prescriptive methodology in the regulation. This approach reflects the philosophy that the regulation only contains the high-level requirements and that the technical details are contained in guidance and updated, as appropriate, to reflect current knowledge. The NRC finds that § 50.67 continues to provide reasonable assurance of adequate protection and safety given new technologies and continued lessons learned. For example, the current § 50.67 requires that the application contain an evaluation of the consequences of applicable design basis accidents. In addition, § 50.90 requires that applications for license amendments fully describe the desired changes. Therefore, applicants and licensees are required to address significant changes to the fuel design such as increases to fuel burnup limits and potential fuel fragmentation, relocation, and dispersal issues, and the NRC will only approve an amendment if the applicant's analysis demonstrates with reasonable assurance that dose values are met, consistent with the agency's process.

IV. 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	Date	ADAMS Accession No. or **Federal Register** citation or web site
PRM–50–122, ''Petition to Amend 10 CFR 50.67, *Accident Source Term,* to Include Methodologies and Release Fractions''.	May 31, 2020	ML20170B161
DG–1199, ''Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors''.	October 2009	ML090960464
SAND2008–6601, ''Analysis of Main Steam Isolation Valve Leakage in Design Basis Accidents Using MELCOR 1.8.6 and RADTRAD''.	October 2008	ML083180196
RG 1.183, ''Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors,'' Revision 0.	July 2000	ML003716792
NUREG–1465, ''Accident Source Terms for Light-Water Nuclear Power Plants''	February 1995	ML041040063
TID–14844, ''Calculation of Distance Factors for Power and Test Reactors''	March 23, 1962	ML021720780
Accident Source Term Methodologies and Corresponding Release Fractions; Notice of Docketing and Request for Comment.	August 24, 2020	85 FR 52058
Comment (002) of Brian Magnuson on PRM–50–122—Accident Source Term Methodologies and Corresponding Release Fractions.	November 8, 2020	ML20330A276
Differing Professional Opinion (DPO) Case File for DPO–2020–002	March 8, 2021	ML21067A645

V. Conclusion

For the reasons cited in this document, the NRC is denying PRM–50–122. The current requirements in § 50.67 continue to provide reasonable assurance of adequate protection of public health and safety and should not be revised as proposed in the PRM.

Dated: July 19, 2022.

For the Nuclear Regulatory Commission.

Brooke P. Clark,

Secretary of the Commission.

[FR Doc. 2022–15854 Filed 7–25–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2022–0105]

RIN 3150–AK84

List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM Flood/Wind Multipurpose Canister Storage System, Certificate of Compliance No. 1032, Amendment No. 8

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its spent fuel storage regulations by revising the Holtec International HI–STORM Flood/Wind Multipurpose Canister Storage System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 8 to Certificate of Compliance No. 1032. Amendment No. 8 revises the description in the certificate of compliance for the Holtec International HI–STORM Flood/Wind system to clearly indicate that only the portions of the components that contact the pool water need to be made of stainless steel or aluminum. Amendment No. 8 also incorporates other minor editorial corrections.

DATES: Submit comments by August 25, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2022–0105, at *https://www.regulations.gov*. If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: William Allen, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6877; email: *William.Allen@nrc.gov* or Andrew G. Carrera, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–1078; email: *Andrew.Carrera@nrc.gov*. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0105 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0105. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov*. For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html*. To begin the search, 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, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2022–0105 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov*. If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on October 11, 2022. However, if the NRC receives any significant adverse comments by August 25, 2022, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For a more detailed discussion of the proposed rule changes and associated analyses, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on March 28, 2011 (76 FR 17019), that approved the Holtec International HI–STORM Flood/Wind Multipurpose Canister Storage System design and added it to the list of NRC-approved cask designs in § 72.214, ''List of approved spent fuel storage casks,'' as Certificate of Compliance No. 1032.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	ADAMS Accession No./ **Federal Register** citation
Direct Final Rule, 10 CFR Part 72, ''List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM Flood/Wind System, Certificate of Compliance No. 1032; [NRC–2011–0007] RIN 3150–AI90, March 28, 2011.	76 FR 17019.
Application from Holtec International for Certificate of Compliance No. 1032, Amendment No. 8, to HI–STORM FW System, July 30, 2021.	ML21211A608 (package).
User Need Memorandum Package to J. Shepherd from Y. Diaz-Sanabria with Proposed Certificate of Compliance No. 1032, Amendment No. 8; Associated Proposed Technical Specifications; Appendices A and B; and the Preliminary Safety Evaluation Report, April 6, 2022.	ML22019A111 (package).

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2022–0105. In addition, the Federal rulemaking

website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2022–0105); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

Dated: July 13, 2022.

For the Nuclear Regulatory Commission.

Daniel H. Dorman,

Executive Director for Operations.

[FR Doc. 2022–15938 Filed 7–25–22; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0810; Project Identifier AD–2021–01238–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all The Boeing Company Model 777 airplanes. This proposed AD was prompted by fuel system reviews conducted by the manufacturer. This proposed AD would require, depending on the airplane configuration, installation of Teflon sleeves, cap sealing of fasteners, detailed inspections, and corrective actions. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate more restrictive airworthiness limitations (AWLs). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 9, 2022.

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 *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 *www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021, is also available at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0810.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0810; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Kevin Nguyen, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3555; email: *kevin.nguyen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0810; Project Identifier AD–2021–01238–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Kevin Nguyen, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3555; email: *kevin.nguyen@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA has examined the underlying safety issues involved in fuel tank explosions on several large transport airplanes, including the adequacy of existing regulations, the service history of airplanes subject to those regulations, and existing maintenance practices for fuel tank systems. As a result of those findings, the FAA issued a regulation titled ''Transport Airplane Fuel Tank System Design Review, Flammability Reduction and Maintenance and Inspection Requirements'' (66 FR 23086, May 7, 2001). In addition to new airworthiness standards for transport airplanes and new maintenance requirements, this rule included Special Federal Aviation Regulation No. 88 (SFAR 88), Amendment 21–78. Subsequently, SFAR 88 was amended by Amendment 21–82 (67 FR 57490, September 10, 2002; corrected at 67 FR 70809, November 26, 2002) and Amendment 21–83 (67 FR 72830, December 9, 2002; corrected at 68 FR 37735, June 25, 2003, to change ''21–82'' to ''21–83'').

Among other actions, SFAR 88 requires certain type design (*i.e.,* type certificate (TC) and supplemental type certificate (STC)) holders to substantiate that their fuel tank systems can prevent ignition sources in the fuel tanks. This requirement applies to type design holders for large turbine-powered

transport airplanes and for subsequent modifications to those airplanes. It requires them to perform design reviews and to develop design changes and maintenance procedures if their designs do not meet the new fuel tank safety standards. As explained in the preamble to the rule, the FAA intended to adopt airworthiness directives to mandate any changes found necessary to address unsafe conditions identified as a result of these reviews.

In evaluating these design reviews, the FAA has established four criteria intended to define the unsafe conditions associated with fuel tank systems that require corrective actions. The percentage of operating time during which fuel tanks are exposed to flammable conditions is one of these criteria. The other three criteria address the failure types under evaluation: Single failures, combination of failures, and unacceptable (failure) experience. For all three failure criteria, the evaluations included consideration of previous actions taken that may mitigate the need for further action.

The FAA has determined that the actions identified in this proposed AD are necessary to reduce the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

The FAA issued AD 2017–11–14, Amendment 39–18913 (82 FR 25954, June 6, 2017) (AD 2017–11–14), for certain The Boeing Company Model 777–200, –200LR, –300, and –300ER series airplanes, to prevent arcing inside the main and center fuel tanks in the event of a fault current or lightning strike, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

AD 2017–11–14 requires certain inspections for certain airplanes, corrective actions if necessary, and installation of Teflon sleeves under certain wire bundle clamps.

Since the FAA issued AD 2017–11–14, it was discovered that more airplanes are affected by the identified unsafe condition, and additional work is required for airplanes on which an earlier revision of the service information was done.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021. This service information specifies applicable actions that vary depending on the airplane configuration, such as procedures for the installation of Teflon sleeves, cap sealing of fasteners, detailed inspections, and corrective actions. The detailed inspection of and installation of Teflon sleeves includes various locations, such as the rear spar wire bundles, inboard and outboard front spar wire bundles, wing-to-body fairing and environmental control system (ECS) bay wire bundles, front and rear spar bulkhead wire bundles, and wing rear spar wire bundles. The detailed inspection of and cap sealing of fasteners include fasteners in the center fuel tank, left and right main fuel tanks, and right cheek portion of the center fuel tank. Corrective actions include installing Teflon sleeve, installing clamp, and cap sealing fasteners.

The FAA also reviewed Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622W001–9, dated March 2022, of Boeing 777 200/200LR/300/300ER/777F Maintenance Planning Data (MPD) Document. This service information specifies, among other airworthiness limitations, 28–AWL–31 and 28–AWL–32 that address cushion clamps and Teflon sleeving installed on out-of-tank wire bundles installed on brackets that are mounted directly on the fuel tanks.

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 **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would require doing all applicable actions (*i.e.,* installation of Teflon sleeves, cap sealing of fasteners, detailed inspections, and corrective actions) identified in Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate AWLs 28–AWL–31 and 28–AWL–32 as identified in Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622W001–9, dated March 2022. For information on the procedures and compliance times for the applicable actions specified in paragraph (g) of this AD, see Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021, at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0810.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections) and Critical Design Configuration Control Limitations (CDCCLs). Compliance with these actions and CDCCLs is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (m) of this proposed AD.

This NPRM would not supersede AD 2017–11–14. Rather, the FAA has determined that a stand-alone AD would be more appropriate to address the changes. Accomplishment of the actions required by paragraph (g) of this proposed AD would then terminate the requirements of paragraphs (g)(1), (i), and (j) of AD 2017–11–14.

In addition, accomplishment of the revision required by paragraph (i) of this proposed AD would terminate the requirements of paragraphs (g)(6) and (h) of AD 2021–24–12, Amendment 39–21833 (86 FR 73660, December 28, 2021) (AD 2021–24–12). AD 2021–24–12 requires revising the existing maintenance or inspection program, as applicable, to incorporate multiple AWLs, including 28–AWL–31 and 28–AWL–32.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 282 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS *

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Installations, cap sealing, and inspections.	Up to 545 work-hours × $85 per hour = $46,325.	Up to $3,510	Up to $49,835	Up to $14,053,470.

* Table does not include estimated costs for revising the existing maintenance or inspection program.

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the FAA estimates the average total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

The FAA estimates the following costs to do any necessary corrective actions that would be required based on the results of the proposed inspections. The agency has no way of determining the number of aircraft that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Corrective actions	Up to 26 work-hours × $85 per hour = $2,210	Up to $3,510	Up to $5,720.

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.

The FAA is 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

The FAA 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 this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would 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 adding the following new airworthiness directive:

The Boeing Company: Docket No. FAA–2022–0810; Project Identifier AD–2021–01238–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 9, 2022.

(b) Affected ADs

(1) This AD affects AD 2017–11–14, Amendment 39–18913 (82 FR 25954, June 6, 2017) (AD 2017–11–14).

(2) This AD also affects AD 2021–24–12, Amendment 39–21833 (86 FR 73660, December 28, 2021) (AD 2021–24–12).

(c) Applicability

This AD applies to all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by fuel system reviews conducted by the manufacturer. The FAA is issuing this AD to prevent arcing inside the main and center fuel tanks in the event of a fault current or lightning strike, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

(f) Compliance

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

(g) Required Service Bulletin Actions

For airplanes identified in Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021: Except as specified in paragraph (h) of this AD, at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021, do all applicable actions (*i.e.,* installation of Teflon sleeves, cap sealing of fasteners, detailed inspections, and corrective actions) identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021. Do all applicable corrective actions before further flight.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021, uses the phrase ''the revision 5 date of

this service bulletin'' or ''the revision 6 date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(2) Where circle symbol 1 of sheet 2 of Figures 172, 173, and 174 of Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021, points to the outboard side of rib no. 9 for the locate and cap seal task or the inspection task, as applicable, in step 1 of sheet 3, for this AD, circle symbol 1 points to the seven fasteners located at the inboard side of rib no. 9.

(3) Where circle symbol 1, next to the text ''7 locations,'' of sheet 2 of Figure 175 and Figure 176 of Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021, points to the outboard side of rib no. 9 for the locate and cap seal task or the inspection task, as applicable, in step 1 of sheet 3, for this AD, circle symbol 1, next to the text ''7 locations,'' points to the seven fasteners located at the inboard side of rib no. 9.

(4) Where circle symbol 1, next to the text ''7 locations,'' of sheet 4 of Figure 179 and Figure 180 of Boeing Alert Service Bulletin 777–57A0050, Revision 6, dated August 18, 2021, points to the outboard side of rib no. 9 for the locate and cap seal task or the inspection task, as applicable, in step 1 of sheet 6, for this AD, circle symbol 1, next to the text ''7 locations,'' points to the seven fasteners located at the inboard side of rib no. 9.

(i) Maintenance or Inspection Program Revision

Within 60 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information for 28–AWL–31 and 28–AWL–32 specified in Section D, ''Airworthiness Limitations-Systems,'' including Subsections D.1, of Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622W001–9, dated March 2022, of Boeing 777–200/200LR/300/300ER/777F Maintenance Planning Data (MPD) Document, except as specified in paragraph (j) of this AD. The initial compliance time for doing airworthiness limitation instructions (ALI) task 28–AWL–32 is at the applicable time specified in paragraph (i)(1) or (2) of this AD:

(1) For airplanes having line numbers (L/Ns) 1 through 503 inclusive: Within 3,750 days after accomplishment of the actions specified in Boeing Service Bulletin 777–57A0050, or within 60 months after the effective date of this AD, whichever occurs later.

(2) For airplanes having L/Ns 504 and subsequent: Within 3,750 days after the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness; or within 60 months after the effective date of this AD; whichever occurs later.

(j) Exceptions to the AWLs

The following exceptions apply to 28–AWL–31 and 28–AWL–32 of Section D, ''Airworthiness Limitations—Systems,'' including Subsections D.1 of Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622W001–9, dated March 2022, of Boeing 777–200/200LR/300/300ER/777F Maintenance Planning Data (MPD) Document.

(1) In paragraph 1.i., change ''Front Spar Bulkhead (Center Tank)'' to ''Front Spar Bulkhead (Center Wing Tank Fuel Quantity Greater than 12,400 Gallons).''

(2) In paragraph 1.i.II, change ''For 777–200, 777–200LR, 777–300, and 777–300ER airplanes, L/N 562 and on'' to ''L/N 562 and on, except 777F.''

(3) In paragraph 1.i.III., change ''For 777F airplanes, L/N 718 and on'' to ''For 777F airplanes.''

(4) In paragraph 1.j., change ''Rear Spar Bulkhead (Center Tank)'' to ''Rear Spar Bulkhead (Center Wing Tank Fuel Quantity Greater than 12,400 Gallons).''

(k) No Alternative Actions, Intervals, or Critical Design Configuration Control Limitations (CDCCLs)

After the existing maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections), intervals, or CDCCLs may be used unless the actions, intervals, and CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (m) of this AD.

(l) Terminating Action for Certain Requirements of AD 2017–11–14 and AD 2021–24–12

(1) Accomplishment of the actions required by paragraph (g) of this AD terminates the requirements of paragraphs (g)(1), (i), and (j) of AD 2017–11–14.

(2) Accomplishment of the revision required by paragraph (i) of this AD terminates the requirements of paragraphs (g)(6) and (h) of AD 2021–24–12.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, 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 responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (n)(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 responsible Flight Standards 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 Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, 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.

(n) Related Information

(1) For more information about this AD, contact Kevin Nguyen, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3555; email: *kevin.nguyen@faa.gov.*

(2) For service information identified in this AD, 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 *www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on June 30, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

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FEDERAL TRADE COMMISSION

16 CFR Part 255

Guides Concerning the Use of Endorsements and Testimonials in Advertising

AGENCY: Federal Trade Commission.

ACTION: Proposed changes to guides; request for comments.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is seeking public comment on proposed revisions to its Guides Concerning the Use of Endorsements and Testimonials in Advertising (''the Guides'').

DATES: Comments must be received on or before September 26, 2022.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Invitation to Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Endorsement Guides; P204500'' on your comment and file your comment online at *https://www.regulations.gov.* If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Michael Ostheimer (202–326–2699), *mostheimer@ftc.gov,* Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, Room CC–10603, 600

Pennsylvania Avenue NW, Washington, DC 20580.

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I. Overview of the Current Guides

The Guides, 16 CFR part 255, are designed to assist businesses and others in conforming their endorsement and testimonial advertising practices to the requirements of section 5 of the FTC Act. Although the Guides interpret laws administered by the Commission, and thus are advisory in nature, proceedings to enforce the requirements of law as explained in the Guides can be brought under the FTC Act. In any such proceeding, the Commission would have the burden of proving that a particular use of an endorsement or testimonial was deceptive under the law.

The Guides define both endorsements and testimonials broadly to mean any advertising message that consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. 16 CFR 255.0(b) and (c). The Guides state that endorsements must reflect the honest opinions, findings, beliefs, or experience of the endorser. 16 CFR 255.1(a). Furthermore, endorsements may not contain any representations that would be deceptive, or could not be substantiated, if made directly by the advertiser. *Id.* The Guides state that an advertisement presenting consumer endorsements about the performance of an advertised product will be interpreted as representing that the product is effective for the purpose depicted in the advertisement. 16 CFR 255.2(a). They further advise that an advertisement employing a consumer endorsement on a central or key attribute of a product will be interpreted as representing that the endorser's experience is representative of what consumers will generally achieve. 16 CFR 255.2(b). If an advertiser does not have adequate substantiation that the endorser's experience is representative, the advertisement should clearly and conspicuously disclose what the generally expected performance would be in the depicted circumstances. *Id.*

The Guides define an expert endorser as someone who, as a result of experience, study, or training, possesses knowledge of a particular subject that is superior to that generally acquired by ordinary individuals. 16 CFR 255.0(e). An expert endorser's qualifications must in fact, give him or her the expertise that he or she is represented as possessing with respect to the endorsement. 16 CFR 255.3(a). Moreover, an expert endorsement must be supported by an actual exercise of that expertise and the expert's evaluation of the product must have been at least as extensive as someone with the same degree of expertise would normally need to conduct in order to support the conclusions presented. 16 CFR 255.3(b).

The Guides advise that when there is a connection between the endorser and the seller of the advertised product that might materially affect the weight or credibility of the endorsement (*i.e.,* the connection is not reasonably expected by the audience), such connection must be fully disclosed. 16 CFR 255.5.

Among other things, the Guides also state that: (1) when the advertisement represents that the endorser uses the endorsed product, the endorser must have been a bona fide user of it at the time the endorsement was given, 16 CFR 255.1(c); (2) advertisers are subject to liability for false or unsubstantiated statements made through endorsements, or for failing to disclose material connections between themselves and their endorsers; and endorsers also may be liable for statements made in the course of their endorsements, 16 CFR 255.1(d); (3) advertisements presenting endorsements by what are represented to be ''actual consumers'' should utilize actual consumers, or clearly and conspicuously disclose that the persons are not actual consumers, 16 CFR 255.2(c); and (4) an organization's endorsement must be reached by a process sufficient to ensure that the endorsement fairly reflects the collective judgment of the organization. 16 CFR 255.4.

II. History of the Guides

In December 1972, the Commission published for public comment proposed Guides Concerning the Use of Endorsements and Testimonials in Advertising, 37 FR 25548 (Dec. 1, 1972). Interested parties submitted extensive comment. On May 21, 1975, the Commission promulgated, under the Federal Trade Commission Act (''FTC Act''), 15 U.S.C. 41–58, three sections of the 1972 proposal as final guidelines (16 CFR 255.0, 255.3 and 255.4) and republished three others, in modified form, for additional public comment. 40 FR 22127 (May 21, 1975). The Commission received public comment on the three re-proposed guidelines, as well as on one of the final guidelines. On January 18, 1980, the Commission promulgated three new sections as final guidelines (16 CFR 255.1, 255.2 and 255.5) and modified an example to one of the final guidelines adopted in May 1975 (16 CFR 255.0 Example 4). 45 FR 3870 (Jan. 18, 1980).

As part of its periodic regulatory review, the Commission sought public comment on the Endorsement Guides in January 2007. 72 FR 2214 (Jan. 18, 2007). In November 2008, the Commission discussed the comments it received in 2007, proposed certain revisions to the Guides, and requested comment on those proposed revisions. 73 FR 72374 (Nov. 28, 2008). In October 2009, the Commission substantively amended the Guides, adding what are now 16 CFR 255.0(a), 255.1(d) and 255.2(a), significantly modifying the guidance in 16 CFR 255.0(b), and modifying or adding numerous examples. 74 FR 53124 (Oct. 15, 2009).

In February 2020, again as part of its ongoing regulatory review process, the Commission published a **Federal Register** notice seeking comment on the overall costs, benefits, and regulatory and economic impact of the Guides as well as a number of specific questions focused on the material connections section of the Guides (16 CFR 255.5). 85 FR 10104 (Feb. 21, 2020). In light of the disruption caused by the Coronavirus pandemic, the Commission extended the comment period for two months. 85 FR 19709 (Apr. 8, 2020).

III. Overview of Comments Received in Response to Regulatory Review Notice

The Commission received 108 unique substantive comments in response to its regulatory review notice.[1] Having

[1] Approximately seventy-five comments were submitted by individual consumers, most of whom were apparently university students fulfilling class assignments. The remaining commenters were: American Influencer Council, Inc. (''AIC''); American Financial Services Association (''AFSA''); Amazon.com, Inc. (''Amazon''); Association of National Advertisers (''ANA''); BBB National Programs (''BBB''); Shirley Boyd, Esq. (''Boyd''); Campaign for a Commercial Free-Childhood and Center for Digital Democracy (''CCFC''); Competition and Markets Authority (''CMA''); Consumer Reports; Council for Responsible Nutrition (''CRN''); Common Sense Media (''CSM''); Consumer World (''CW''); Digital Content Next (''DCN''); Esports Bar Association (''Esports Bar''); Entertainment Software Association (''ESA''); Prof. Chris Jay Hoofnagle (''Hoofnagle''); Interactive Advertising Bureau (''IAB''); Jim Dudukovich, Esq. (''Dudukovich''); IZEA Worldwide, Inc. (''IZEA''); Kleinfeld, Kaplan and Becker LLP (''KK&B''); LEGO Group (''LEGO''); Maastricht University (''Maastricht''); Association of Magazine Media (''MPA''); North American Insulation Manufacturers Association (''NAIMA''); internet and Television Association (''NCTA''); NetChoice; News Media

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considered those comments and its own extensive consumer protection experience, the Commission now proposes various amendments to the Guides and invites comments on these proposed changes.

Most commenters noted that the Guides are beneficial and should be retained,[2] and none disagreed. Some comments praised the current Guides for striking an appropriate balance between protecting consumers and allowing advertisers to communicate creatively and effectively to potential customers.[3]

Most comments responded to specific questions the Commission posed in the February 2020 **Federal Register** notice about certain provisions of the current Guides. Those comments are discussed in Part IV, below, in the context of the specific Guide provisions to which they relate.

In addition, some comments addressed other issues. For example, some commenters said that the Commission should engage in more vigorous enforcement activities related to the Guides [4] and greater educational efforts.[5] Other commenters weighed in on whether the Commission should [6] or should not [7] engage in a rulemaking proceeding to convert some principles in the Guides into trade regulation rules.

Some comments urged the Commission to encourage social media platforms to improve or standardize the built-in tools that some of them offer to facilitate disclosures of material connections by platform users.[8] The Commission supports development of effective, built-in disclosure tools but is concerned that some of the existing ones are too poorly contrasting, fleeting, or small, or may be placed in locations where they do not catch the user's attention. For example, a social media disclosure tool that superimposes a disclosure over a posted picture could be poorly contrasting, making the disclosure inadequate, especially if the picture is only displayed for a few seconds and contains competing text or other information. Similarly, a disclosure tool that superimposes a small disclosure in the bottom left corner of a video for only a few seconds is inconspicuous. Even a tool that employs a disclosure of sufficient size, duration, and contrast could be inadequate if it is displayed above, rather than below, a picture or video that catches the attention of users scrolling through their feeds. Platforms may be exposing endorsers to liability if users rely solely on a platform's inadequate tools for their disclosures. Platforms may also be exposing themselves to liability depending on the representations they make about these tools. Given that platforms play a major role in disseminating and monetizing endorsements, and actively encourage endorsers to promote and amplify their posts, the Commission believes they should carefully evaluate their tools and what they say about them to ensure they are not exposing themselves or their users to liability.

IV. Section-by-Section Discussion of Proposed Revisions to Guides, Comments Received in Response to February 2020 Federal Register Notice, and Requests for Additional Comment

The Commission believes the Guides should be retained but a number of revisions are appropriate. Many of the proposed changes are simply clarifications or additional examples of the principles embodied in the existing Guides. Others enunciate basic principles not expressly set forth in the current Guides but are established in Commission enforcement actions. Several represent substantive changes from the current Guides, based upon increased knowledge of how consumers view endorsements and taking into consideration the comments submitted in response to the February 2020 **Federal Register** notice. Some of the new examples and updates to existing examples reflect the extent to which advertisers have turned increasingly to the use of social media and product reviews to market their products.

The Commission seeks comments on these proposed revisions, which are discussed below by Section.[9]

A. § 255.0—Purpose and Definitions

The Guides currently begin with a purpose and definitions section.

Current § 255.0(b) defines an ''endorsement'' as any advertising message that consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. As suggested in a comment, the Commission proposes revising that definition to clarify that ''marketing'' and ''promotional'' messages can be endorsements.[10] When a social media user tags a brand in a post, it generally communicates that the poster uses or likes the brand, so, the revised definition would also indicate that tags in social media posts can be endorsements. Section 255.0(b) also currently states that an ''endorser'' may be an individual, group, or institution. The Commission proposes a modification indicating that an endorser could instead simply appear to be an individual, group, or institution. Thus, the Guides would clearly apply to endorsements by fabricated endorsers.

The Commission proposes to add a footnote to § 255.0(b). It would indicate the availability of detailed staff business guidance regarding endorsements that is updated periodically, while noting that such staff guidance is not approved by or binding upon the Commission. Numerous commenters asked the Commission to update the Guides more frequently, such as every three years.[11] Some commenters asked that the Commission provide detailed guidance in the Guides about acceptable and unacceptable language and placement for disclosures of material connections and their use on particular platforms,[12] while others asked the Commission to continue to allow marketers flexibility in the crafting and placement of necessary disclosures.[13] Commenters also differed on whether to incorporate FTC staff business guidance into the Guides, with some saying it would be useful [14] and others taking the position that the social media landscape is ever-changing and the Guides should focus on general principles.[15] One commenter

Alliance (''NMA''); National Retail Federation (''NRF''); Performance-Driven Marketing Institute (''PDMI''); Pharmavite LLC (''Pharmavite''); Performance Marketing Association (''PMA''); Princeton University Center for Information Technology Policy and University of Chicago Department of Computer Science researchers (''Princeton''); SuperAwesome; and Truth in Advertising, Inc. (''TINA''). The comments are available online at *https://beta.regulations.gov/document/FTC-2020-0017-0001/comment.*

[2] *See, e.g.,* Amazon at 3; ANA at 1–3; BBB at 2; CRN at 1; DCN at 1; Dudukovich at 3; Esports Bar at 2–3; ESA at 2; IAB at 1–2; IZEA at 1; LEGO at 1; MPA at 2; NAIMA at 1–2; NCTA at 1–2; NMA at 2; and Pharmavite at 1.

[3] *See, e.g.,* Amazon at 3; ESA at 2; IAB at 2–3; MPA at 2; NCTA at 1–2; and PDMI at 2.

[4] *See, e.g.,* Boyd at 5–6, 16; Consumer Reports at 2; IZEA at 1; NRF at 14; and TINA at 22–23.

[5] *See, e.g.,* AIC at 4–5; Amazon at 3; Dudukovich at 6; and IAB at 3.

[6] *See, e.g.,* Boyd at 5–7; Natalie Jacobwith at 3.

[7] *See, e.g.,* MPA at 4, 7–8; and NRF at 14.

[8] *See, e.g.,* AFSA at 2; AIC at 2–3; ANA at 5–6; Dudukovich at 11–12; IAB at 4; NCTA at 9; NRF at 9; PMA at 2; and Princeton at 5; *see also* CMA at 3.

[9] Non-substantive changes to improve readability or to update examples to reflect changes in marketing methods, technology, or society that have occurred since the Guides were last updated or since they were first written (*e.g.,* replacing ''brochure'' with ''web page'') are not discussed below.

[10] *See* Boyd at 7.

[11] *See, e.g.,* AIC at 1, 3; and Pharmavite at 2.

[12] *See, e.g.,* CRN at 2–4; Pharmavite at 1–2; PMA at 2; and Anna Keltner at 3.

[13] *See, e.g.,* ESA at 5–6; IAB at 2–3; and MPA at 6–7.

[14] *See, e.g.,* Consumer Reports at 9; CRN at 2; Dudukovich at 9; Pharmavite at 1–2; and TINA at 12.

[15] *See, e.g.,* ANA at 3; BBB at 3; and NCTA at 2.

suggested cross-referencing staff guidance in the Guides.[16] The Commission believes that its current approach for endorsement-related guidance makes sense, with the Guides focused on general principles and examples, and the more informal and easily updated staff guidance focused on specific questions and issues that arise in this area. The new footnote would ensure that people reading the Guides are aware of this additional staff guidance.

Current § 255.0(d) defines a ''product'' as any product, service, company or industry. At the suggestion of a commenter,[17] the Commission proposes modifying the definition to clarify that a ''product'' includes a ''brand.''

In response to comments requesting further guidance on what constitutes a clear and conspicuous disclosure, the Commission proposes adding a new definition of ''clear and conspicuous'' in a new § 255.0(f). It would define a ''clear and conspicuous'' disclosure as a disclosure that ''is difficult to miss (*i.e.,* easily noticeable) and easily understandable by ordinary consumers.'' It would give specific guidance with respect to visual and audible disclosures, stress the importance of ''unavoidability'' when the communication involves social media or the internet, and say that the disclosure should not be contradicted or mitigated by, or inconsistent with, anything in the communication. While not mandating that a disclosure be both visual and audible under all circumstances, it would say that when the triggering claim is visual the disclosure should be at least visual; that when the triggering claim is audible, the disclosure should be at least audible; that when the triggering claim is both visual and audible, the disclosure should be both; and that a simultaneous audible and visual disclosure is more likely to be clear and conspicuous. Finally, the proposed definition notes that when an endorsement targets a specific audience, such as older adults, its effectiveness will be evaluated from the perspective of members of that group.

Example 1 to § 255.0 currently provides an example of an endorsement and illustrates the principle that an endorsement may not be presented out of context or reworded so as to distort the endorser's opinion. One commenter noted that it was unclear in the example who distorted the endorser's opinion.[18] The Commission proposes to modify the example to clearly identify the responsible party.

Current Example 5 to § 255.0 involves a television advertisement in which a professional golfer implicitly endorses a brand of golf balls by being shown practicing her swing using the balls, even though she says nothing in the ad. The Commission proposes expanding this example to illustrate that use of the same video footage in a social media post can be an endorsement as long as the endorsed brand is tagged or otherwise readily identifiable by viewers.

Example 6 to § 255.0 currently illustrates how a paid actor hosting a product infomercial and reading from a script can still be making an endorsement. The Commission proposes adding a scenario to this example to show how the same actor can talk about the product without making an endorsement and deleting Example 7, which had also focused on illustrating statements that were not endorsements.

Example 8 to § 255.0, which would be renumbered as Example 7, currently provides scenarios in which an individual consumer's social media posts would and would not be considered endorsements. Two commenters asked for further explanation of the Commission's reasoning.[19] The Commission proposes to clarify the example. When a consumer buys the product with her own money under ordinary circumstances and chooses to post about it, the post is not an endorsement under the Guides because the consumer has no connection to the manufacturer beyond being an ordinary purchaser and her message cannot be attributed to the product's manufacturer. The revised example would note that the same would be true for a consumer review. Furthermore, if the consumer received a coupon for a free trial product from the manufacturer simply based upon her purchase history and if the manufacturer did not ask coupon recipients for reviews, then the consumer's unsolicited review would not be an endorsement because it cannot be attributed to the manufacturer. However, if the consumer received the free product as part of a marketing program that periodically provides free products from various manufacturers, where the consumer has the option of writing a review, the consumer's review would be an endorsement because of her connection to the manufacturer through the marketing program.

The Commission proposes adding six new examples to this section. New Example 8 would illustrate an endorsement made through video game play streamed on social media without an express product recommendation. New Example 9 illustrates disclosures that are easily missed and thus are not clear and conspicuous. New Examples 10 and 11 illustrate how a disclosure may need to be evaluated from the perspective of an advertisement's target audience and that disclosures need to be clear and conspicuous on multiple common types of platforms or devices.

New Example 12 derives in part from a commenter's suggestion that the Guides address an incentivized endorser denigrating a competitor's product.[20] The example would state that a fake negative review or another paid or incentivized negative statement about a competitor's service does not meet the definition of an ''endorsement.'' It would note, however, that engaging in such disparagement can be a deceptive practice.

New Example 13 derives from a commenter's suggestion that the Guides state, as alleged in *FTC* v. *Devumi, LLC,*[21] that it is illegal to sell, purchase, or use bots or other fake social media accounts to market goods and services.[22] Because such indicators do not express an advertising message by their mere presence, the example would acknowledge that an endorser's use of fake indicators of social media influence is not itself an endorsement issue. The Commission would note in the example that it is a deceptive practice for users of social media to purchase or create indicators of social media influence and then use them to misrepresent their influence for a commercial purpose and that it is a deceptive practice to sell or distribute such indicators to such users.

B. § 255.1—General Considerations

Section 255.1 sets forth principles that apply to endorsements generally (*e.g.,* endorsements must reflect the honest opinions or experience of the endorser, and they may not convey any representation that would be deceptive if made directly by the advertiser).

Section 255.1(d) currently recognizes that advertisers are subject to liability for false or unsubstantiated statements made through endorsements, or for failing to disclose material connections between themselves and their endorsers. The Commission would indicate that an advertiser may be liable for an

[16] *See* TINA at 12.

[17] *See* Boyd at 7.

[18] *See* Dudukovich at 17.

[19] *See* ANA at 8–9; and Dudukovich at 17–18.

[20] *See* NAIMA at 5; *see also* Consumer Reports at 4.

[21] *See* Complaint at 5, *FTC* v. *Devumi, LLC,* No. 9:19–cv–81419–RKA (S.D. Fla. Oct. 18, 2019), *https://www.ftc.gov/system/files/documents/cases/devumi_complaint.pdf.*

[22] *See* Consumer Reports at 9.

endorser's deceptive statement even when the endorser is not liable. The Commission also proposes adding guidance to this subsection on what actions advertisers should take with respect to their endorsers. Such guidance previously only appeared in an example.

Current § 255.1(d) also recognizes that endorsers themselves may be subject to liability for their statements. Commenters asked for clarification of when endorsers would be liable.[23] The Commission proposes moving the discussion of endorser liability to a new § 255.1(e) and indicating that endorsers may be liable for their statements such as when they make representations that they know or should know to be deceptive. The level of due diligence required by the endorsers will depend on their level of expertise and knowledge, among other factors. Current Examples 3 and 4 involve endorsers who knew or should have known that their statements were deceptive. Section 255.1(e) would also say that a non-expert endorser may also be liable when the endorser makes misleading or unsubstantiated representations about performance or efficacy that are inconsistent with the endorser's personal experience or that were not made or approved by the advertiser and that go beyond the scope of the endorser's personal experience.[24] Current Example 5 involves such an endorser and the Commission proposes updating it to better illustrate this principle. Finally, § 255.1(e) would also note that endorsers may also be liable for failing to disclose unexpected material connections between themselves and an advertiser, such as when they create and disseminate endorsements without such disclosures.

A few commenters suggested that the Guides deal with the disclosure responsibility of intermediaries such as marketing and public relations firms.[25] The Commission proposes adding a new § 255.1(f) explaining the potential liability of intermediaries. Intermediaries, such as advertising agencies and public relations firms, may be liable for their roles in disseminating what they knew or should have known were deceptive endorsements.[26] For example, advertising agencies that intentionally engage in deception or that ignore obvious shortcomings of claims they disseminate may be liable. They may also be liable for their roles with respect to endorsements that fail to disclose unexpected material connections, whether by disseminating advertisements without necessary disclosures of material connection or by hiring and directing the endorsers who fail to make necessary disclosures.[27]

The Commission proposes adding a new § 255.1(g) stating a general principle that the use of an endorsement with the image or likeness of a person other than the actual endorser is deceptive if it misrepresents a material attribute of the endorser.

The Commission proposes modifying current Example 1 to § 255.1 to note that an endorser does not need to go back and modify or delete past social media posts as long as the posts were not misleading when they were made and the dates of the posts are clear and conspicuous to viewers. However, the example would state that if the post was later reposted by the endorser or shared by the publisher, it would suggest to reasonable consumers that the endorser continued to hold the views expressed in the prior post.

The Commission proposes deleting current Example 2 to § 255.1 because it is patently obvious that a person asked to try unmarked products and pick the best one is not communicating that she or he is a regular user of the selected product. The Commission proposes to replace that example with one that illustrates when an endorsement would likely communicate regular use and ownership.

The Commission proposes editing current Example 3 to § 255.1 to indicate that a paid endorser and the company paying the endorser are both potentially liable for the endorser's social media post that fails to disclose the endorser's relationship to the company. The Commission proposes altering the example and adding a new cross-reference in this example to the Guides' material connection provisions (§ 255.5) to make clear that those provisions apply to paid consultants and not just employees or those hired to be endorsers. The Commission also proposes adding alternative language to the example illustrating how the advertiser could be liable when the endorser is not liable.

The Commission proposes adding new Examples 6 and 7 to illustrate the principle in new § 255.1(g) involving the use of an image or likeness of a person other than the actual endorser to misrepresent a material attribute of the endorser. These examples involve endorsements for an acne product using an image of a person with much better skin than the actual endorser, a weight-loss product with an image of a person weighing much less than the actual endorser, and a learn-to-read program with a picture of a significantly younger child than the child of the endorser.

C. § 255.2—Consumer Endorsements

Section 255.2 of the Guides provides guidance specific to the use of consumer endorsements, commonly referred to as testimonials.

Current § 255.2(a) addresses the need for adequate substantiation for claims made through endorsements. The Commission proposes clarifying that this need for substantiation applies to both express and implied claims.

Current § 255.2(b) states that when the advertiser does not have substantiation that an endorser's experience is representative of what consumers will generally achieve, an ad should clearly and conspicuously disclose the generally expected performance in the depicted circumstances. The Commission proposes adding a clarifying statement that the disclosure of the generally expected performance should be presented in a manner that does not itself misrepresent what consumers can expect.

The Commission proposes adding a new § 255.2(d) that addresses consumer reviews and articulates a fundamental principle not expressly set forth in the existing Guides. It would state that in procuring, suppressing, boosting, organizing, or editing consumer reviews of their products, advertisers should not take actions that have the effect of distorting or otherwise misrepresenting what consumers think of their products. It would also note that this is true regardless of whether the reviews are considered ''endorsements'' under the Guides.

The Commission proposes to expand current Example 2 of § 255.2 so as to illustrate how a disclosure of expected results can be misleading when those results are only true under limited circumstances not clearly stated in the ad.

Because current Example 3 of § 255.2 involves serum cholesterol lowering claims, the Commission proposes replacing ''adequate substantiation''

[23] *See, e.g.,* Boyd at 13; and Dudukovich at 18.

[24] The Commission would add a cross-reference to § 255.3 with respect to the responsibilities of an expert endorser.

[25] *See, e.g.,* Boyd at 13; and Maastricht at 7–8.

[26] *See* Complaint at 6, 8, 12–12, 20, *FTC* v. *Marketing Architects, Inc.,* No. 2:18–cv–00050 (D. Me. Feb. 6, 2018), *https://www.ftc.gov/system/files/documents/cases/1623101marketingarchitects complaint.pdf* (defendant advertising agency created and disseminated fictitious weight-loss testimonials).

[27] *See* Complaint at 2–5, *In the Matter of Machinima, Inc.,* No. C–4569 (Sept. 2, 2015), *https://www.ftc.gov/system/files/documents/cases/160317machinimacmpt.pdf.* (respondent recruited, hired, and instructed influencers on behalf of an advertiser, but did not require the influencers to disclose compensation).

with ''competent and reliable scientific evidence,'' the type of substantiation that would be required for such claims.

Current Example 4 of § 255.2 provides two examples of acceptable weight-loss disclosures of generally expected results under different circumstances, one where a testimonialist reports her weight loss over a certain period and one where the testimonialist reports her weight loss without specifying a time period. The Commission proposes editing those disclosures to make them more informative for consumers.[28] The Commission would also add examples of two alternative disclosures that would be inadequate, one involving a disclosure of weight loss per week and the other involving a broad range of possible weight loss.

Another proposed addition to Example 4 discusses and illustrates how outliers can substantially affect the average results such that a disclosure of generally expected results based upon a mean computation would be misleading and how, when such is the case, the disclosure could instead be based upon median results.

The Commission would also add language to Example 4 illustrating a marketer's liability for procuring fake reviews that appear for its product on a third-party review website. The marketer is not only liable for procuring reviews that are not from bona fide users, but is also liable for any unsubstantiated claims made in those fake reviews.[29]

Finally, the Commission proposes adding an alternative scenario to Example 4 involving an advertisement for a weight-loss program. The addition would explain that a disclosure of typical weight loss limited to only successful participants in the program (*e.g.,* only those who stuck with it for six months), ignoring participants who quit, would be inadequate.

The Commission proposes four new examples to illustrate the proposed new § 255.2(d).

New Example 8 addresses an online seller suppressing or not publishing product reviews based upon their star ratings or their negative sentiments.[30] The review portions of the seller's product pages are misleading as to purchasers' actual opinions of the products. The example would also provide examples of reviews that need not be published. The Commission would note that sellers are not required to display customer reviews that contain unlawful, harassing, abusive, obscene, vulgar, or sexually explicit content, or content that is inappropriate with respect to race, gender, sexuality, or ethnicity, or reviews that the seller reasonably believes are fake, so long as the criteria for withholding reviews are applied uniformly to all reviews submitted. The footnote would also note that sellers are not required to display reviews that are unrelated to their products or services and that ''services'' include customer service, delivery, returns, and exchanges. The Commission is particularly interested in consumer expectations regarding product reviews that are solely about related services. Do consumers expect that sellers publish such reviews that are just about a product's shipping or refund practices or the associated customer service together with other product reviews? Finally, the example illustrates that it would be deceptive for a seller to highlight glowing reviews and label them as ''most helpful'' if consumers had not actually voted them most helpful.

New Example 9 addresses paying purchasers to write positive product reviews.[31] Such reviews are deceptive regardless of any disclosure of the payment, because the manufacturer has required that the reviews be positive. The proposed example has a cross-reference for when there is no requirement that the reviews be positive and the reviewers understand that they are free to write negative reviews without suffering any consequences.

New Example 10 addresses the unfair practice of threatening consumers who post negative reviews to third-party websites in order to coerce the consumers to delete their reviews. Such threats can take the form of legal,[32] physical, or other threats. As noted in a new proposed footnote to the Guides, when the threats are incorporated into a form contract, they violate the Consumer Review Fairness Act. 15 U.S.C. 45b(b)(1).

Several commenters suggested addressing review gating, *i.e.,* practices that involve obtaining customer feedback and then sending satisfied and dissatisfied customers down different paths in order to encourage positive reviews and avoid negative reviews.[33] New Example 11 discusses a marketer soliciting feedback from all customers and only inviting those who give positive feedback to write online reviews. It says that such disparate treatment may be an unfair or deceptive practice if it results in the posted reviews being substantially more positive than if the marketer had not engaged in the practice.

D. § 255.3—Expert Endorsements

Section 255.3 provides guidance with respect to expert endorsements.

Current § 255.3(a) addresses advertisements that represent ''directly or by implication'' that an endorser is an expert with respect to the endorsement message. The Commission proposes clarifying that this section applies to representations made ''expressly or by implication.''[34] The Commission proposes modifying current Example 2 to clarify that the non-medical ''doctor'' expert endorser should have relevant expertise and that the non-medical and non-specialized doctors referenced in the example do not necessarily have enough expertise to endorse the product even with a clear and conspicuous disclosure. The Commission also proposes amending current Example 6—adding a sentence about the potential liability of the expert endorser and the advertiser, including a cross-reference to § 255.1. The Commission would clarify that what matters is the expert's ''purported'' degree of expertise, not the expert's actual degree of expertise. Finally, the Commission would also indicate in Example 6 that scientific evidence is expected to support a serum cholesterol lowering claim.

E. § 255.4—Endorsements by Organizations

Section 255.4 provides guidance specific to the use of endorsements by organizations.

The Commission proposes to renumber the current example in § 255.4 as Example 1 and to add two additional examples.

New Example 2 would say that if a manufacturer sets up an apparently independent review website that reviews the manufacturer's own

[28] Example 4 provides an example of a performance claim requiring substantiation—a claim that WeightAway is an effective weight loss product. The Commission proposes revising that exemplar to include the claim that the endorser's weight loss was not just due to her dietary restrictions and exercise regimen.

[29] *See* Complaint at 5–9, *FTC* v. *Cure Encapsulations, Inc.,* No. 1:19–cv–00982 (E.D.N.Y. Feb. 26, 2019), *https://www.ftc.gov/system/files/documents/cases/quality_encapsulations_complaint_2-26-19.pdf.*

[30] *See* Complaint at 1–2, *In the Matter of Fashion Nova, LLC,* No. C–4759 (Mar. 18, 2022), *http://www.ftc.gov/system/files/ftc_gov/pdf/1923138C4759FashionNovaComplaint.pdf.*

[31] *See* Complaint at 8, *In the Matter of UrthBox, Inc.,* No. C–4676 (April 3, 2019), *https://www.ftc.gov/system/files/documents/cases/172_3028_urthbox_complaint_4-3-19_0.pdf.*

[32] *See FTC* v. *Roca Labs, Inc.,* 345 F. Supp. 3d 1375, 1394–95 (M.D. Fla. 2018).

[33] *See, e.g.,* BBB at 5; Boyd at 23; Dudukovich at 13; and TINA at 22; *but see* ANA at 14.

[34] The Commission proposes making a similar change to § 255.2(c).

products and competing products, that website is deceptive because it is not in fact independent.[35]

New Example 3 addresses a third-party review site that provides rankings of various manufacturers' products and accepts payments in exchange for higher rankings. This practice was challenged in the Commission's case against LendEDU.[36] One commenter asked whether, based on that case, a disclosure is only required on such websites when they make claims that they are ''objective,'' ''accurate,'' and ''unbiased.''[37] The revised example would say that a paid ranking boost is deceptive regardless of whether the website makes an express claim of independence or objectivity. It also would note the potential lability of a manufacturer that pays for a higher ranking. Finally, it would say that if a manufacturer makes payments to the review site but not for higher rankings, there should be a clear and conspicuous disclosure regarding the payments, with a cross-reference to an example involving payments for affiliate links.

F. § 255.5—Disclosure of Material Connections

Section 255.5 of the current Guides states that advertisers must disclose connections between themselves and their endorsers that might materially affect the weight or credibility of the endorsement (*i.e.,* the connection is not reasonably expected by the audience). The text of this section also includes the example of a television ad featuring an endorser who is neither represented in the advertisement as an expert nor is known to a significant portion of the viewing public.

The Commission believes the requirement that material connections between advertisers and endorsers be disclosed is appropriate and should be retained. The Commission proposes specifying that such disclosures must be ''clear and conspicuous,'' adding a definition of that phrase (as discussed above), and deleting the more ambiguous statement that such disclosures must be ''fully'' disclosed. It also proposes to delete the existing example from the text of the section and to replace it with more general guidance. A commenter asked for further guidance about what types of relationships could constitute material connections.[38] The proposed revised text of § 255.5 would explain that material connections can include a business, family, or personal relationship; monetary payment; the provision of free or discounted products or services to the endorser, including products or services unrelated to the endorsed product; early access to a product; or the possibility of winning a prize, of being paid, or of appearing on television or in other media promotions. The new guidance would state that a material connection can exist regardless of whether the advertiser requires an endorsement for the payment or free or discounted products.

Several commenters asked that the Commission provide examples of immaterial connections that need no disclosure.[39] The Commission proposes instead to recognize in the text of § 255.5 that some connections may be immaterial because they are too insignificant to affect the weight or credibility given to endorsements.

One commenter suggested that the Guides recognize that, for influencers primarily famous because of their social media presence, their sponsorships are often expected.[40] Without accepting or rejecting that proposition, the Commission proposes stating that an endorser's material connection need not to be disclosed when it is understood or expected by all but an insignificant portion of the audience.

One commenter requested that the Guides state that the exact nature or amount of an endorser's compensation need not be disclosed,[41] while another commenter asked that the Guides require influencers to state the amount of their compensation because it will help star-struck consumers appreciate the lack of honesty in celebrity posts.[42] The Commission proposes clarifying that the disclosure of a material connection does not require the complete details of the connection, but it must clearly communicate the nature of the connection sufficiently for consumers to evaluate its significance.

Commenters also expressed widely diverging opinions on the extent to which the Guides should address disclosures of material connections to children. Most of these commenters agreed that, as children grow, they are better able to understand what advertisements are and to distinguish them from other content. They also agreed that it is easier for children to recognize traditional television advertising than influencer marketing, with its blurring of organic content and marketing. Commenters diverged as to the ages at which and the extent to which disclosures can be effective. Some variously argued that disclosures of material connections are never effective for children, are ineffective at certain young ages, or should be more robust for children at certain ages.[43] At least one commenter argued that disclosures can work for younger kids.[44] Several commenters urged the Commission not to address this issue in the Guides at all and rely instead on self-regulatory organizations.[45] One commenter also noted that improving disclosures can help parents identify advertising to children.[46] Some commenters discussed or cited research studies in this area to support their views[47] or referred to the value of additional research.[48]

The Commission recognizes that it is difficult for children—especially younger children—to discern ads from entertainment or other content in the digital environment, where the lines are blurred much more than in traditional ''linear'' media, like television. For example, it may not be apparent to them when influencers are being paid to promote a product featured in their video and social media posts. Although not addressed in the comments, parents may play a role in promoting children's understanding of advertising and lessening the effects of potentially deceptive practices. The Commission would benefit from more evidence than provided in the comments to develop specific guidance or best practices in this area. FTC staff thus plans to hold a public event to gather research and expert opinion on: (a) children's capacities at different ages and developmental stages to recognize and understand advertising content and distinguish it from other content; (b) the need for and efficacy of disclosures as a solution to the problem facing children of different ages; and, (c) if disclosures can be efficacious, the most effective format, placement, and wording for disclosures. As discussed below, the Commission also proposes

[35] *See* Complaint at 8–9, *In the Matter of Son Le,* No. C–4619 (May 31, 2020), *https://www.ftc.gov/system/files/documents/cases/162_3178_c4619_trampolinesafetyofamerica_complaint_0.pdf.*

[36] *See* Complaint at 15, *In the Matter of Shop Tutors, Inc.,* No. C–4719 (Feb. 3, 2020), *https://www.ftc.gov/system/files/documents/cases/182_3180_lendedu_complaint.pdf.*

[37] *See* AFSA at 2.

[38] *See* Boyd at 9.

[39] *See, e.g.,* ANA at 10–12; CMA at 2; and NCTA at 10.

[40] *See* NRF at 4.

[41] *Id.* at 10.

[42] *See* Hoofnagle at 3.

[43] *See* CCFC at 3, 25; CSM at 1, 10; and TINA at 10–11.

[44] *See* SuperAwesome at 2; *see also* NetChoice at 11.

[45] *See* ANA at 9–10; DCN at 2; IAB at 5; and NCTA at 2–3.

[46] *See* CCFC at 23.

[47] *See, e.g.,* CCFC at 16–17, 21–23; CSM at 3–4, 6, 9; SuperAwesome at 3–5; and TINA at 10–11.

[48] *See, e.g.,* BBB at 4; and CSM at 10.

adding a new § 255.6 addressing endorsements directed to children.

The current Example 3 to § 255.5 makes clear that consumers would not expect that a celebrity was paid for endorsing a medical procedure during a routine interview on a television talk show, that knowledge of such a financial interest would likely affect the weight or credibility consumers give to that endorsement, and that the celebrity's financial connection to the advertiser should be disclosed. One commenter said that the Guides should indicate that disclosures at the end of a talk show are not clear and conspicuous.[49] The Commission proposes edits to Example 3 noting that the disclosure should be during the interview and that a disclosure during the show's closing credits is not clear and conspicuous. A different commenter suggested that the Guides say that disclosure obligations exist even if an endorser is not paid for a particular post.[50] Revised Example 3 would say that, if the celebrity makes the endorsement in one of her social media posts, her connection to the advertiser should be disclosed regardless of whether she was paid for the particular post. The revised example would also illustrate that receipt of free or discounted services can constitute a material connection.

One comment suggested that the Guides address the reuse of an influencer's social media endorsement.[51] Revised Example 3 would also state that, when reusing a celebrity's social media posts in its own social media, an advertiser should clearly and conspicuously disclose its relationship to the celebrity (assuming the initial post necessitated a disclosure).

The current Example 4 to § 255.5 addresses the consumer expectation that an expert endorser would be reasonably compensated for appearing in an ad. The Commission proposes clarifying that the existing guidance applies to traditional ads, such as television ads, and adding an alternative scenario involving a post on the expert's own social media account, a context in which consumers would be less likely to expect that the expert was compensated and more likely to expect that the expert is expressing an independent opinion.

The current Example 5 to § 255.5 addresses a scenario in which restaurant patrons are informed before they enter that they will be interviewed by an advertiser as part of its TV promotion of its new food product. A commenter suggested that we clarify why this information is material.[52] The Commission proposes explaining that a patron might want to give the product a good review in the hope of appearing on television.

Several commenters said that incentivized reviews need disclosures even if the incentives are not conditioned on the reviews being positive.[53] Current Example 6 to § 255.5 addresses the situation where ''extras'' who want to work in commercials are recruited to use a product and endorse it in an infomercial in exchange for compensation and exposure. The Commission proposes expanding the example to address ordinary consumers recruited to try a product for free and write online reviews of it in exchange for payment; the example would state the need to disclose this connection in the resulting reviews. The example has a cross-reference to § 255.2(d) and Example 9 of § 255.2 for situations in which an incentive is conditioned on a review being positive or recruited consumers have reason to believe there are or may be negative consequences from posting reviews which are not positive. Multiple comments also raised concerns regarding incentivized reviews being included in an average star rating.[54] The proposed example states that, even if adequate disclosures appear in each incentivized review, the practice could still be deceptive if those solicited reviews' star ratings are included in an average star rating for the product, and their inclusion materially increases that average star rating.

The Commission proposes to modify Example 7 to § 255.5 to say that if a significant proportion of viewers are likely unaware that a woodworking influencer received a valuable piece of equipment for free from its manufacturer, he should clearly and conspicuously disclose that he got it for free. The Commission would make this example conditional in recognition of the possibility that the followers of some influencers or types of influencers may expect that they receive free products from advertisers. The Commission would also add a cross-reference to § 255.1(d) about the liability and responsibilities of advertisers.

The current Example 8 to § 255.5 addresses an employee's endorsement of an employer's product in an online community and the resulting need for a disclosure. A comment asked that the Commission add a statement about the employer educating its employees about disclosure requirements. The Commission proposes adding an explanation of an employer's obligations and noting that this guidance also applies to online consumer reviews.

The Commission is also proposing the addition of three new examples to § 255.5.

The first one arises from the request of commenters that the Commission include an example illustrating conditions under which third-party certifications and seals of approval, which typically require payment to the certifying organization to fund the evaluation, do not require a disclosure.[55] New Example 10, which is a slightly edited version of an example in the Green Guides,[56] recognizes that consumers would reasonably expect that marketers have to pay non-profit, third-party organizations reasonable fees for some certifications and seals.

Second, multiple commenters asked that the Guides address the need to disclose affiliate relationships and the adequacy of affiliate links[57] while one commenter asserted that consumers understand such links and that no disclosure is necessary.[58] New Example 11 addresses the disclosure of affiliate links. It says that a blogger who writes independent content reviewing products and who monetizes that content with affiliate links should clearly and conspicuously disclose the compensation.

Third, new Example 12 recognizes that, just as with television commercials, consumers can reasonably expect that people appearing in certain newer-form advertisements are compensated for their statements.

G. New § 255.6—Endorsements Directed to Children

As discussed above, endorsements directed to children may be of special concern. The Commission proposes adding a section simply acknowledging that fact, as to which we are aware of no disagreement. It would state, ''Endorsements in advertisements addressed to children may be of special concern because of the character of the audience. Practices which would not

[49] *See* CW at 2–5.

[50] *See* Dudukovich at 30, 62.

[51] *See* IZEA at 1.

[52] *See* Dudukovich at 24–25.

[53] *See, e.g.,* AFSA at 3–4; BBB at 4–5; Boyd at 21–22; Dudukovich at 12–13; NAIMA at 4–5; and TINA at 21; *but see* CRN at 4–5.

[54] *See, e.g.,* AFSA at 4; BBB at 5; NAIMA at 5; and TINA at 21–22.

[55] *See* CRN at 4; and KK&B at 1–2; *see also* NAIMA at 4.

[56] *See* Guides for the Use of Environmental Marketing Claims, 16 CFR 290.6, Example 8.

[57] *See, e.g.,* AFSA at 4; BBB at 5, 11–12; Boyd at 24–25; CRN at 3, Consumer Reports at 10; Dudukovich at 14, 52; Maastricht at 7; and NMA at 3.

[58] *See* NRF at 10.

ordinarily be questioned in advertisements addressed to adults might be questioned in such cases.'' The Commission proposed a very similar section in 1972 as § 255.6,[59] but withdrew it in 1975, stating that it had ''determined that the area of children's advertising could not be completely covered in these Guides.'' [60] The Commission now believes that even as more evidence is gathered about the effects of children's advertising, there is ample basis to recognize that children may react differently than adults to endorsements in advertising or to related disclosures.

Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before September 26, 2022. Write ''Endorsement Guides; P204500'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website. To ensure the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write ''Endorsement Guides; P204500'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580.

Because your comment will be placed on the public record, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not contain sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential''—as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments it receives on or before September 26, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

List of Subjects in 16 CFR Part 255

Advertising, Trade practices.

■ Accordingly, the Federal Trade Commission proposes to revise 16 CFR part 255 to read as follows:

PART 255—GUIDES CONCERNING USE OF ENDORSEMENTS AND TESTIMONIALS IN ADVERTISING

Sec.

255.0 Purpose and definitions.
255.1 General considerations.
255.2 Consumer endorsements.
255.3 Expert endorsements.
255.4 Endorsements by organizations.
255.5 Disclosure of material connections.
255.6 Endorsements directed to children.

Authority: 38 Stat. 717, as amended; 15 U.S.C. 41–58.

§ 255.0 Purpose and definitions.

(a) The Guides in this part represent administrative interpretations of laws enforced by the Federal Trade Commission for the guidance of the public in conducting its affairs in conformity with legal requirements. Specifically, the Guides address the application of section 5 of the FTC Act (15 U.S.C. 45) to the use of endorsements and testimonials in advertising. The Guides provide the basis for voluntary compliance with the law by advertisers and endorsers. Practices inconsistent with these Guides may result in corrective action by the Commission under section 5 if, after investigation, the Commission has reason to believe that the practices fall within the scope of conduct declared unlawful by the statute. The Guides set forth the general principles that the Commission will use in evaluating endorsements and testimonials, together with examples illustrating the application of those principles. The Guides do not purport to cover every possible use of endorsements in advertising.[1] Whether a particular endorsement or testimonial is deceptive will depend on the specific factual circumstances of the advertisement at issue.

(b) For purposes of this part, an ''endorsement'' means any advertising, marketing, or promotional message (including verbal statements, tags in social media posts, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the ''endorser'' and could be or appear to be an individual, group, or institution.

(c) The Commission intends to treat endorsements and testimonials identically in the context of its enforcement of the Federal Trade Commission Act and for purposes of

[59] *See* 37 FR 25,548 (Dec. 1, 1972).

[60] *See* 40 FR 22,127 (May 1, 1975).

[1] Staff business guidance applying section 5 of the FTC Act to endorsements and testimonials in advertising is available on the FTC website. Such staff guidance addresses details not covered in these Guides and is updated periodically but is not approved by or binding upon the Commission.

this part. The term endorsements is therefore generally used hereinafter to cover both terms and situations.

(d) For purposes of this part, the term ''product'' includes any product, service, brand, company, or industry.

(e) For purposes of this part, an ''expert'' is an individual, group, or institution possessing, as a result of experience, study, or training, knowledge of a particular subject, which knowledge is superior to what ordinary individuals generally acquire.

(f) For purposes of this part, ''clear and conspicuous'' means that a disclosure is difficult to miss (*i.e.,* easily noticeable) and easily understandable by ordinary consumers. If a communication's representation necessitating a disclosure is made through visual means, the disclosure should be made in at least the communication's visual portion; if the representation is made through audible means, the disclosure should be made in at least the communication's audible portion; and if the representation is made through both visual and audible means, the disclosure should be made in the communication's visual and audible portions. A disclosure presented simultaneously in both the visual and audible portions of a communication is more likely to be clear and conspicuous. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, should stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood. An audible disclosure should be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it. In any communication using an interactive electronic medium, such as social media or the internet, the disclosure should be unavoidable. The disclosure should not be contradicted or mitigated by, or inconsistent with, anything else in the communication. When an endorsement targets a specific audience, such as older adults, ''ordinary consumers'' includes members of that group.

(g) Examples:

(1) *Example 1.* A film critic's review of a movie is excerpted in an advertisement placed by the film's producer. When so used, the excerpt is an endorsement because readers would view it as a statement of the critic's own opinions and not those of the producer. If the excerpt alters or quotes from the text of the review in a way that does not fairly reflect its substance, the advertisement would be deceptive because it distorts the endorser's opinion. (*See* § 255.1(b))

(2) *Example 2.* A television commercial depicts two unidentified shoppers in a supermarket buying a laundry detergent. One comments to the other how clean the advertised brand makes the shopper's clothes. The other shopper then replies, ''I will try it because I have not been fully satisfied with my own brand.'' This obviously fictional dramatization would not be an endorsement.

(3) *Example 3.* In an advertisement for a pain remedy, an announcer unfamiliar to consumers except as a spokesperson for the advertising drug company praises the drug's ability to deliver fast and lasting pain relief. The spokesperson purports to speak, not on the basis of their own opinions, but rather in the place of and on behalf of the drug company. The announcer's statements would not be considered an endorsement.

(4) *Example 4.* A manufacturer of automobile tires hires a well-known professional automobile racing driver to deliver its advertising message in television commercials. In these commercials, the driver speaks of the smooth ride, strength, and long life of the tires. Many consumers are likely to believe this message reflects the driver's personal views, even if the driver does not say so, because consumers recognize the speaker as primarily a racing driver and not merely as a spokesman. Accordingly, consumers may well believe the driver would not speak for an automotive product without actually believing in their statements and having personal knowledge sufficient to form the beliefs expressed. The attribution of these beliefs to the driver makes this message an endorsement under the Guides.

(5) *Example 5.* (i) A television advertisement for a brand of golf balls includes a video of a prominent and well-recognized professional golfer practicing numerous drives off the tee. The video would be an endorsement even though the golfer makes no verbal statement in the advertisement.

(ii) The golfer is also hired to post the video to their social media account. The post is an endorsement if viewers can readily identify the golf ball brand, either because it is apparent from the video or because it is tagged or otherwise mentioned in the post.

(6) *Example 6.* (i) An infomercial for a home fitness system is hosted by a well-known actor. During the infomercial, the actor demonstrates the machine and states, ''This is the most effective and easy-to-use home exercise machine that I have ever tried. Even if the actor is reading from a script, the statement would be an endorsement, because consumers are likely to believe it reflects the actor's personal views.

(ii) Assume that, rather than speaking about their experience with or opinion of the machine, the actor says that the machine was designed by exercise physiologists at a leading university, that it isolates each of five major muscle groups, and that it is meant to be used for fifteen minutes a day. After demonstrating various exercises using the machine, the actor finally says how much the machine costs and how to order it. As the actor does not say or do anything during the infomercial that would lead viewers to believe that the actor is expressing their own views about the machine, there is no endorsement.

(7) *Example 7.* (i) A consumer who regularly purchases a particular brand of dog food decides one day to purchase a new, more expensive brand made by the same manufacturer. The purchaser posts to their social media account that the change in diet has made their dog's fur noticeably softer and shinier, and that in her opinion, the new dog food definitely is worth the extra money. Because the consumer has no connection to the manufacturer beyond being an ordinary purchaser, their message cannot be attributed to the manufacturer and the post would not be deemed an endorsement under the Guides. The same would be true if the purchaser writes a consumer product review on the manufacturer's website, a retailer's website, or an independent review website.

(ii) Assume that rather than purchase the dog food with their own money, the consumer receives it for free because the store routinely tracks purchases and the dog food manufacturer arranged for the store to provide a coupon for a free trial bag of its new brand to all purchasers of its existing brand. The manufacturer does not ask coupon recipients for product reviews and recipients likely would not assume that the manufacturer expects them to post reviews. The consumer's post would not be deemed an endorsement under the Guides because this unsolicited review cannot be attributed to the manufacturer.

(iii) Assume now that the consumer joins a marketing program under which participants periodically receive free products from various manufacturers and can write reviews if they want to do so. If the consumer receives a free bag of the new dog food through this program, their positive review would be considered an endorsement under the Guides because of their connection to the manufacturer through the marketing program.

(8) *Example 8.* A college student, who has earned a reputation as an excellent video game player, live streams their game play. The developer of a new video game pays the student to play and live stream its new game. The student plays the game and appears to enjoy it. Even though the college student does not expressly recommend the game, the game play is considered an endorsement.

(9) *Example 9.* (i) An influencer who is paid to endorse a vitamin product in their social media posts discloses their connection to the product's manufacturer only on the profile pages of their social media accounts. The disclosures are not clear and conspicuous because people seeing their paid posts could easily miss the disclosures.

(ii) Assume now that the influencer discloses their connection to the manufacturer in the posts themselves, but that, in order to see the disclosures, consumers have to click on a link labeled simply ''more.'' Those disclosures are not clear and conspicuous.

(iii) Assume now that the influencer relies solely upon a social media platform's built-in disclosure tool for one of these posts. The disclosure appears in small white text, it is set against the light background of the image that the influencer posted, it competes with unrelated text that the influencer superimposed on the image, and the post appears for only five seconds. The disclosure is easy to miss and thus not clear and conspicuous.

(10) *Example 10.* A television advertisement promotes a smartphone app that purportedly halts cognitive decline. The ad presents multiple endorsements by older senior citizens who are represented as actual consumers who used the app. The advertisement discloses via both audio and visual means that the persons featured are actors. Because the advertisement is targeted at older consumers, whether the disclosure is clear and conspicuous will be evaluated from the perspective of older consumers, including those with diminished auditory, visual, or cognitive processing abilities.

(11) *Example 11.* (i) A social media advertisement promoting a cholesterol-lowering product features a testimonialist who says how says by how much they lowered their serum cholesterol. The claimed reduction greatly exceeds what is typically experienced by users of the product and a disclosure of typical results is required. The marketer has been able to identify from online data collection Spanish speaking individuals with high cholesterol levels who are unable to understand English and microtargets a Spanish-language version of the ad to them, disclosing the typical results in English. The adequacy of the disclosure will be evaluated from the perspective of the targeted individuals.

(ii) Assume now that the ad has a disclosure that is clear and conspicuous when viewed on a computer browser but that is not clear and conspicuous when the ad is rendered on a smartphone. Because some consumers will view the ad on their smartphones, the disclosure is inadequate.

(12) *Example 12.* An exterminator purchases fake negative reviews of competing exterminators. A paid or otherwise incentivized negative statement about a competitor's product is not an endorsement, as that term is used in the Guides. Nevertheless, such statements, *e.g.,* a paid negative review of a competing product, can be deceptive in violation of section 5.

(13) *Example 13.* A motivational speaker buys fake social media followers to impress potential clients. The use by endorsers of fake indicators of social media influence, such as fake social media followers, is not itself an endorsement issue. The Commission notes, however, that it is a deceptive practice for users of social media platforms to purchase or create indicators of social media influence and then use them to misrepresent such influence to potential clients, purchasers, investors, partners, or employees or to anyone else for a commercial purpose. It is also a deceptive practice to sell or distribute such indicators to such users.

§ 255.1 General considerations.

(a) Endorsements must reflect the honest opinions, findings, beliefs, or experience of the endorser. Furthermore, an endorsement may not convey any express or implied representation that would be deceptive if made directly by the advertiser (*see* § 255.2(a) and (b) regarding substantiation of representations conveyed by consumer endorsements).

(b) An advertisement need not present an endorser's message in the exact words of the endorser unless the advertisement presents the endorsement as a quotation. However, the endorsement may not be presented out of context or reworded so as to distort in any way the endorser's opinion or experience with the product. An advertiser may use an endorsement of an expert or celebrity only so long as it has good reason to believe that the endorser continues to subscribe to the views presented. An advertiser may satisfy this obligation by securing the endorser's views at reasonable intervals where reasonableness will be determined by such factors as new information about the performance or effectiveness of the product, a material alteration in the product, changes in the performance of competitors' products, and the advertiser's contract commitments.

(c) When the advertisement represents that the endorser uses the endorsed product, the endorser must have been a bona fide user of it at the time the endorsement was given. Additionally, the advertiser may continue to run the advertisement only so long as it has good reason to believe that the endorser remains a bona fide user of the product (*see* § 255.1(b) regarding the ''good reason to believe'' requirement).

(d) Advertisers are subject to liability for misleading or unsubstantiated statements made through endorsements when there is a connection between the advertiser and the endorser, or for failing to disclose unexpected material connections between themselves and their endorsers (*see* § 255.5). An advertiser may be liable for an endorser's deceptive statement even when the endorser is not liable. Advertisers should:

(1) Provide guidance to their endorsers on the need to ensure that their statements are not misleading and to disclose unexpected material connections;

(2) Monitor their endorsers' compliance; and

(3) Take action sufficient to remedy non-compliance and prevent future non-compliance.

(e) Endorsers may be liable for statements made in the course of their endorsements, such as when an endorser makes a representation that the endorser knows or should know to be deceptive. Also, an endorser who is not an expert may be liable for misleading or unsubstantiated representations regarding a product's performance or effectiveness when the representations are inconsistent with the endorser's personal experience, or were not made or approved by the advertiser and go beyond the scope of the endorser's personal experience (for the responsibilities of an endorser who is an expert, *see* § 255.3). Endorsers may also be liable for failing to disclose unexpected material connections between themselves and an advertiser, such as when an endorser creates and disseminates endorsements without such disclosures.

(f) Intermediaries, such as advertising agencies and public relations firms, may

be liable for their roles in disseminating what they knew or should have known were deceptive endorsements. They may also be liable for their roles with respect to endorsements that fail to disclose unexpected material connections, whether by disseminating advertisements without necessary disclosures or by hiring and directing endorsers who fail to make necessary disclosures.

(g) The use of an endorsement with the image or likeness of a person other than the actual endorser is deceptive if it misrepresents a material attribute of the endorser.

(h) Examples:

(1) *Example 1.* (i) A building contractor states in an advertisement disseminated by an advertiser, ''I use XYZ exterior house paint because of its remarkable quick drying properties and durability.'' This endorsement must comply with the pertinent requirements of § 255.3. Subsequently, the advertiser reformulates its paint to enable it to cover exterior surfaces with only one coat. Prior to continued use of the contractor's endorsement, the advertiser must contact the contractor in order to determine whether the contractor would continue to use the paint and to subscribe to the views presented previously.

(ii) Assume that, before the reformulation, the contractor had posted an endorsement of the paint to their social media account. Even if the contractor would not use or recommend the reformulated paint, there is no obligation to modify or delete their post as long as the date of that post is clear and conspicuous to viewers. If the contractor reposts or the advertiser shares the contractor's original endorsement after the reformulation, consumers would expect that the contractor continued to hold the views expressed in the original post.

(2) *Example 2.* In a radio advertisement, a well-known DJ talks about how much they enjoy making coffee with a particular coffee maker in the morning. The DJ's comments likely communicate that they own and regularly use the coffee maker. If they do not own it or used it only during a demonstration by its manufacturer, the ad would be deceptive.

(3) *Example 3.* (i) A dermatologist is a paid advisor to a pharmaceutical company and is asked by the company to post about its products on their professional social media account. The dermatologist posts that the company's newest acne treatment product is ''clinically proven'' to work. Before giving the endorsement, the dermatologist received a write-up of the clinical study in question, which indicates flaws in the design and conduct of the study that are so serious that they preclude any conclusions about the efficacy of the product. Given their medical expertise, the dermatologist should have recognized the study's flaws and is subject to liability for their false statements made in the advertisement. The advertiser is also liable for the misrepresentation made through the endorsement (*see* § 255.3 regarding the product evaluation that an expert endorser must conduct). Even if the study was sufficient to establish the product's proven efficacy, the pharmaceutical company and the dermatologist are both potentially liable if the endorser fails to disclose their relationship to the company (*see* § 255.5 regarding the disclosure of unexpected material connections).

(ii) Assume that the expert had asked the pharmaceutical company for the evidence supporting its claims and there were no apparent design or execution flaws in the study shown to the expert, but that the pharmaceutical company had withheld a larger and better controlled, non-published proprietary study of the acne treatment which failed to find any statistically significant improvement in acne. The expert's ''clinically proven'' to work claim would be deceptive and the company would be liable for the claim, but because the dermatologist did not have a reason to know that the claim was deceptive, the expert would not be liable.

(4) *Example 4.* A well-known celebrity appears in an infomercial for a hot air roaster that purportedly cooks a chicken perfectly in twenty minutes. During the shooting of the infomercial, the celebrity watches five attempts to cook chickens using the roaster. In each attempt, the chicken is undercooked after twenty minutes and requires forty-five minutes of cooking time. In the commercial, the celebrity places an uncooked chicken in the roaster. The celebrity then takes from a second roaster what appears to be a perfectly cooked chicken, tastes the chicken, and says that if you want perfect chicken every time, in just twenty minutes, this is the product you need. A significant percentage of consumers are likely to believe the statement represents the celebrity's own view and experience even though the celebrity is reading from a script. Because the celebrity knows that their statement is untrue, the endorser is subject to liability. The advertiser is also liable for misrepresentations made through the endorsement.

(5) *Example 5.* (i) A skin care products advertiser hires an influencer to promote its products on the influencer's social media account. The advertiser requests that the influencer try a new body lotion and post a video review of it. The advertiser does not provide the influencer with any materials stating that the lotion cures skin conditions and the influencer does not ask the advertiser if it does. However, believing that the lotion cleared up their eczema, the influencer says in their review, ''This lotion cures eczema. All of my followers suffering from eczema should use it.'' The advertiser is subject to liability for misleading or unsubstantiated representations made through the influencer's endorsement. Furthermore, the influencer, who did not limit their claims to their personal experience and did not have a reasonable basis for their claim that the lotion cures eczema, is subject to liability for the misleading or unsubstantiated representation in endorsement. The influencer and the advertiser may also be liable if the influencer fails to disclose clearly and conspicuously being paid for the endorsement (*see* § 255.5).

(ii) In order to limit its potential liability, the advertiser should provide guidance to its influencers concerning the need to ensure that statements they make are truthful and substantiated and the need to disclose unexpected material connections and take other steps to discourage or prevent non-compliance. The advertiser should also monitor its influencers' compliance and take steps necessary to remove and halt the continued publication of deceptive representations when they are discovered and to ensure the disclosure of unexpected material connections (*see* §§ 255.1(d) and 255.5).

(6) *Example 6.* (i) The website for an acne treatment features accurate testimonials of users who say that the product improved their acne quickly and with no side effects. Instead of using images of the actual endorsers, the website accompanies the testimonials with pictures of different individuals with near perfect skin. The images misrepresent the improvements to the endorsers' complexions.

(ii) The same website also sells WeightAway shakes and features an accurate testimonial from an individual who says, ''I lost 50 pounds by just drinking the shakes.'' Instead of accompanying the testimonial with a picture of the actual endorser, who went from 300 pounds to 250 pounds, the website shows a picture of an individual who appears to weigh about 100 pounds. By suggesting that WeightAway

shakes caused the endorser to lose one-third of their original body weight, the image misrepresents the product's effectiveness. Even if it is accompanied by a picture of the actual endorser, the testimonial could still communicate a deceptive typicality claim.

(7) *Example 7.* A learn-to-read program disseminates a sponsored social media post by a parent saying that the program helped their child learn to read. The picture accompanying the post is not of the endorser and their child. The testimonial is from the parent of a 7-year-old, but the post shows an image of a child who appears to be only 4 years old. By suggesting that the program taught a 4-year-old to read, the image misrepresents the effectiveness of the program.

§ 255.2 Consumer endorsements.

(a) An advertisement employing endorsements by one or more consumers about the performance of an advertised product or service will be interpreted as representing that the product or service is effective for the purpose depicted in the advertisement. Therefore, the advertiser must possess and rely upon adequate substantiation, including, when appropriate, competent and reliable scientific evidence, to support express and implied claims made through endorsements in the same manner the advertiser would be required to do if it had made the representation directly, *i.e.,* without using endorsements. Consumer endorsements themselves are not competent and reliable scientific evidence.

(b) An advertisement containing an endorsement relating the experience of one or more consumers on a central or key attribute of the product or service will likely be interpreted as representing that the endorser's experience is representative of what consumers will generally achieve with the advertised product or service in actual, albeit variable, conditions of use. Therefore, an advertiser should possess and rely upon adequate substantiation for this representation. If the advertiser does not have substantiation that the endorser's experience is representative of what consumers will generally achieve, the advertisement should clearly and conspicuously disclose the generally expected performance in the depicted circumstances, and the advertiser must possess and rely on adequate substantiation for that representation. The disclosure of the generally expected performance should be presented in a manner that does not itself misrepresent what consumers can expect.

(c) Advertisements presenting endorsements by what are represented, expressly or by implication, to be ''actual consumers'' should utilize actual consumers in both the audio and video, or clearly and conspicuously disclose that the persons in such advertisements are not actual consumers of the advertised product.

(d) In procuring, suppressing, boosting, organizing, or editing consumer reviews of their products, advertisers should not take actions that have the effect of distorting or otherwise misrepresenting what consumers think of their products, regardless of whether the reviews are considered endorsements under the Guides.

(e) Examples:

(1) *Example 1.* (i) A web page for a baldness treatment consists entirely of testimonials from satisfied customers who say that after using the product, they had amazing hair growth and their hair is as thick and strong as it was when they were teenagers. The advertiser must have competent and reliable scientific evidence that its product is effective in producing new hair growth.

(ii) The web page will also likely communicate that the endorsers' experiences are representative of what new users of the product can generally expect. Therefore, even if the advertiser includes a disclaimer such as, ''Notice: These testimonials do not prove our product works. You should not expect to have similar results,'' the ad is likely to be deceptive unless the advertiser has adequate substantiation that new users typically will experience results similar to those experienced by the testimonialists.

(2) *Example 2.* (i) An advertisement disseminated by a company that sells heat pumps presents endorsements from three individuals who state that after installing the company's heat pump in their homes, their monthly utility bills went down by $100, $125, and $150, respectively. The ad will likely be interpreted as conveying that such savings are representative of what consumers who buy the heat pump can generally expect. The advertiser does not have substantiation for that representation because, in fact, fewer than 20% of purchasers will save $100 or more. A disclosure such as, ''Results not typical'' or ''These testimonials are based on the experiences of a few people and you are not likely to have similar results'' is insufficient to prevent this ad from being deceptive because consumers will still interpret the ad as conveying that the specified savings are representative of what consumers can generally expect.

(A) In another context, the Commission tested the communication of advertisements containing testimonials that clearly and prominently disclosed either ''Results not typical'' or the stronger ''These testimonials are based on the experiences of a few people and you are not likely to have similar results.'' Neither disclosure adequately reduced the communication that the experiences depicted are generally representative. Based upon this research, the Commission believes that similar disclaimers regarding the limited applicability of an endorser's experience to what consumers may generally expect to achieve are unlikely to be effective. Although the Commission would have the burden of proof in a law enforcement action, the Commission notes that an advertiser possessing reliable empirical testing demonstrating that the net impression of its advertisement with such a disclaimer is non-deceptive will avoid the risk of the initiation of such an action in the first instance.

(B) The advertiser should clearly and conspicuously disclose the generally expected savings and have adequate substantiation that homeowners can achieve those results. There are multiple ways that such a disclosure could be phrased, *e.g.,* ''the average homeowner saves $35 per month,'' ''the typical family saves $50 per month during cold months and $20 per month in warm months,'' or ''most families save 10% on their utility bills.''

(ii) Disclosures like those in *Example 2(i)(B)* could still be misleading, however, if they only apply to limited circumstances that are not described in the advertisement. For example, if the advertisement does not limit its claims by geography, it would be misleading if the disclosure of expected results in a nationally disseminated advertisement was based on the experiences of customers in a southern climate and the experiences of those customers was much better than could be expected by heat pump users in a northern climate.

(3) *Example 3.* An advertisement for a cholesterol-lowering product features individuals who claim that their serum cholesterol went down by 120 points and 130 points, respectively; the ad does not mention the endorsers having made any lifestyle changes. A well-conducted clinical study shows that the product reduces the cholesterol levels of individuals with elevated cholesterol by an average of 15% and the advertisement clearly and conspicuously discloses this fact. Despite the presence of this disclosure, the advertisement would be deceptive if

the advertiser does not have competent and reliable scientific evidence that the product can produce the specific results claimed by the endorsers (*i.e.,* a 130-point drop in serum cholesterol without any lifestyle changes).

(4) *Example 4.* (i) An advertisement for a weight-loss product features a formerly obese person. The endorser says in the ad, ''Every day, I drank 2 WeightAway shakes, ate only raw vegetables, and exercised vigorously for six hours at the gym. By the end of six months, I had gone from 250 pounds to 140 pounds.'' The advertisement accurately describes the endorser's experience, and such a result is within the range that would be generally experienced by an extremely overweight individual who consumed WeightAway shakes, only ate raw vegetables, and exercised as the endorser did. Because the endorser clearly describes the limited and truly exceptional circumstances under which they achieved the claimed results, the ad is not likely to convey that consumers who weigh substantially less or use WeightAway under less extreme circumstances will lose 110 pounds in six months. If the advertisement simply says that the endorser lost 110 pounds in six months using WeightAway together with diet and exercise, however, this description would not adequately alert consumers to the truly remarkable circumstances leading to the endorser's weight loss. The advertiser must have substantiation, however, for any performance claims conveyed by the endorsement (*e.g.,* that WeightAway is an effective weight loss product and that the endorser's weight loss was not caused solely by their dietary restrictions and exercise regimen).

(ii) If, in the alternative, the advertisement simply features ''before'' and ''after'' pictures of a woman who says ''I lost 50 pounds in 6 months with WeightAway,'' the ad is likely to convey that the endorser's experience is representative of what consumers will generally achieve. Therefore, if consumers cannot generally expect to achieve such results, the ad would be deceptive. Instead, the ad should clearly and conspicuously disclose what they can expect to lose in the depicted circumstances (*e.g.,* ''women who use WeightAway for six months typically lose 15 pounds''). A disclosure such as ''Average weight loss is 1–2 pounds per week'' is inadequate and likely deceptive. It does not communicate the period over which such weight loss can be expected and likely implies that such weight loss continues at that rate indefinitely.

(iii) If the ad features the same pictures but the testimonialist simply says, ''I lost 50 pounds with WeightAway,'' and WeightAway users generally do not lose 50 pounds, the ad should disclose what results they do generally achieve (*e.g.,* ''women who use WeightAway lose 15 pounds on average''). A disclosure such as ''most women who use WeightAway lose between 10 and 50 pounds'' is inadequate because the range specified is so broad that it does not sufficiently communicate what users can generally expect.

(iv) Assume that a WeightAway advertisement contains a disclosure of generally expected results that is based upon the mean weight loss of users. If the mean is substantially affected by outliers, then the disclosure would be misleading. For example, if the mean weight loss is 15 pounds, but the median weight loss is 8 pounds, it would be misleading to say that the average weight loss was 15 pounds. In such cases, the disclosure's use of median weight loss instead could help avoid deception, *e.g.,* ''most users lose 8 pounds'' or ''the typical user loses 8 pounds.''

(v) Assume that WeightAway's manufacturer procured a fake consumer review, reading ''I lost 50 pounds with WeightAway,'' and had it published on a third-party review website. This endorsement is deceptive because it was not written by a bona fide user (*see* § 255.1(c)). Moreover, the manufacturer would need competent and reliable scientific evidence that WeightAway is capable of causing 50-pound weight loss.

(vi) Assume that WeightAway is a diet and exercise program and a person appearing in a WeightAway ad says, ''I lost 50 pounds in 6 months with WeightAway.'' Very few WeightAway users lose 50 pounds in 6 months and the ad discloses, ''The typical weight loss of WeightAway users who stick with the program for 6 months is 35 pounds.'' In fact, only one-fifth of those who start the WeightAway program stick with it for 6 months. The disclosure is inadequate because it does not communicate what the typical outcome is for users who start the program. In other words, even with the disclosure, the ad does not communicate what people who join the WeightAway program can generally expect.

(5) *Example 5.* An advertisement presents the results of a poll of consumers who have used the advertiser's cake mixes as well as their own recipes. The results purport to show that the majority believed that their families could not tell the difference between the advertised mix and their own cakes baked from scratch. Many of the consumers are pictured in the advertisement along with relevant, quoted portions of their statements endorsing the product. This use of the results of a poll or survey of consumers represents that this is the typical result that ordinary consumers can expect from the advertiser's cake mix.

(6) *Example 6.* An advertisement appears to show a ''hidden camera'' situation in a crowded cafeteria at breakfast time. A spokesperson for the advertiser asks a series of patrons of the cafeteria for their spontaneous, honest opinions of the advertiser's recently introduced breakfast cereal. Even though none of the patrons is specifically identified during the advertisement, the net impression conveyed to consumers may well be that these are actual customers. If actors have been employed, this fact should be clearly and conspicuously disclosed.

(7) *Example 7.* (i) An advertisement for a recently released motion picture shows three individuals coming out of a theater, each of whom gives a positive statement about the movie. These individuals are actual consumers expressing their personal views about the movie. The advertiser does not need to have substantiation that their views are representative of the opinions that most consumers will have about the movie. Because the consumers' statements would be understood to be the subjective opinions of only three people, this advertisement is not likely to convey a typicality message.

(ii) If the motion picture studio had approached these individuals outside the theater and offered them free tickets if they would talk about the movie on camera afterwards or post about it on social media, that arrangement should be clearly and conspicuously disclosed (*see* § 255.5).

(8) *Example 8.* (i) A camping goods retailer's website has various product pages. Each product page provides consumers with the opportunity to review the product and rate it on a five-star scale. Each such page displays the product's average star rating and a breakdown of the number of reviews with each star rating, followed by individual consumers' reviews and ratings. As such, the website is representing that it is providing an accurate reflection of the view of the purchasers who submitted product reviews to the website. If the retailer chose to suppress or otherwise not publish any reviews with fewer than four stars or reviews that contain negative sentiments, the product pages

would be misleading as to purchasers' actual opinions of the products.

(ii) If the retailer chose not to post reviews containing profanity, that would not be unfair or deceptive even if reviews containing profanity tend to be negative reviews. However, it would be misleading if the retailer blocked only negative reviews containing profanity, but posted positive reviews containing profanity. It would be acceptable for the retailer to have a policy against posting reviews unrelated to the product at issue or related services, for example reviews complaining about the owner's policy positions. But it would be misleading if the retailer chose to filter reviews based on other factors that are only a pretext for filtering them based on negativity. Sellers are not required to display customer reviews that contain unlawful, harassing, abusive, obscene, vulgar, or sexually explicit content, or content that is inappropriate with respect to race, gender, sexuality, or ethnicity, or reviews that the seller reasonably believes are fake, so long as the criteria for withholding reviews are applied uniformly to all reviews submitted. Neither are sellers required to display reviews that are unrelated to their products or services. Customer service, delivery, returns, and exchanges are related to the seller's products and services.

(iii) Assume now, that each product page starts with a glowing five-star review that is labeled as ''the most helpful review.'' Labeling the review as the most helpful suggests it was voted most helpful by consumers visiting the website. If the initial review on each such page was selected by the retailer and was not selected as the most helpful review by other consumers, labeling it as the most helpful would be deceptive.

(9) *Example 9.* A manufacturer offers to pay genuine purchasers $20 each to write positive reviews of its products on third-party review websites. Such reviews are deceptive even if the payment is disclosed because their positive nature is required by, rather than being merely influenced by, the payment. If, however, the manufacturer did not require the reviews to be positive and the reviewers understood that there were no negative consequences from writing negative reviews, a clear and conspicuous disclosure of the material connection would be appropriate (*see* § 255.5 and § 255.6 (f)(2) (Example 6)).

(10) *Example 10.* A manufacturer threatens consumers who post negative reviews of its products to third-party review websites with legal action or with physical threats in order to coerce the consumers to delete their reviews. Such threats amount to an unfair practice because consumers would be misled as to purchasers' actual opinions of the product.[2]

(11) *Example 11.* A marketer contacts recent online, mail-order, and in-store purchasers of its products and asks them to provide feedback to the marketer. The marketer then invites purchasers who give very positive feedback to post online reviews of the products on third-party websites. Less pleased and unhappy purchasers are simply thanked for their feedback. Such a practice may be an unfair or deceptive practice if it results in the posted reviews being substantially more positive than if the marketer had not engaged in the practice. If, in the alternative, the marketer had simply invited all recent purchasers to provide feedback on third-party websites, the solicitation would not have been unfair or deceptive, even if it had expressed its hope for positive reviews.

§ 255.3 Expert endorsements.

(a) Whenever an advertisement represents, expressly or by implication, that the endorser is an expert with respect to the endorsement message, then the endorser's qualifications must in fact give the endorser the expertise that the endorser is represented as possessing with respect to the endorsement.

(b) Although an expert may, in endorsing a product, take into account factors not within the endorser's expertise (such as taste or price), the endorsement must be supported by an actual exercise of that expertise in evaluating product features or characteristics with respect to which the endorser has expertise and which are relevant to an ordinary consumer's use of or experience with the product. This evaluation must have included an examination or testing of the product at least as extensive as someone with the same degree of expertise would normally need to conduct in order to support the conclusions presented in the endorsement. To the extent that the advertisement implies that the endorsement was based upon a comparison to another product or other products, such comparison must have been included in the expert's evaluation; and as a result of such comparison, the expert must have concluded that, with respect to those features on which the endorser is expert and which are relevant and available to an ordinary consumer, the endorsed product is at least equal overall to the competitors' products. Moreover, where the net impression created by the endorsement is that the advertised product is superior to other products with respect to any such feature or features, then the expert must in fact have found such superiority (*see* § 255.1(e) regarding the liability of endorsers).

(c) Examples:

(1) *Example 1.* An endorsement of a particular automobile by one described as an ''engineer'' implies that the endorser's professional training and experience are such that the endorser is well acquainted with the design and performance of automobiles. If the endorser's field is, for example, chemical engineering, the endorsement would be deceptive.

(2) *Example 2.* An endorser of a hearing aid is simply referred to as ''Doctor'' during the course of an advertisement. The ad likely implies that the endorser is a medical doctor with substantial experience in the area of hearing. If the endorser is not a medical doctor with substantial experience in audiology, the endorsement would likely be deceptive. A non-medical ''doctor'' (*e.g.,* an individual with a Ph.D. in audiology) or a physician without substantial experience in the area of hearing might be able to endorse the product, but at minimum, the advertisement must clearly and conspicuously disclose the nature and limits of the endorser's expertise

(3) *Example 3.* A manufacturer of automobile parts advertises that its products are approved by the ''American Institute of Science.'' From its name, consumers would infer that the ''American Institute of Science'' is a bona fide independent testing organization with expertise in judging automobile parts and that, as such, it would not approve any automobile part without first testing its efficacy by means of valid scientific methods. If the American Institute of Science is not such a bona fide independent testing organization (*e.g.,* if it was established and operated by an automotive parts manufacturer), the endorsement would be deceptive. Even if the American Institute of Science is an independent bona fide expert testing organization, the endorsement may nevertheless be deceptive unless the Institute has conducted valid scientific tests of the advertised products and the test results support the endorsement message.

(4) *Example 4.* A manufacturer of a non-prescription drug product represents that its product has been

[2] The Consumer Review Fairness Act makes it illegal for companies to include standardized contract provisions that threaten or penalize people for posting honest reviews. 15 U.S.C. 45b.

selected over competing products by a large metropolitan hospital. The hospital has selected the product because the manufacturer, unlike its competitors, has packaged each dose of the product separately. This package form is not generally available to the public. Under the circumstances, the endorsement would be deceptive because the basis for the hospital's choice—convenience of packaging—is neither relevant nor available to consumers, and the basis for the hospital's decision is not disclosed to consumers.

(5) *Example 5.* A person who is identified as the president of a commercial ''home cleaning service'' states in a television advertisement that the service uses a particular brand of cleanser, instead of leading competitors it has tried, because of this brand's performance. Because cleaning services extensively use cleansers in the course of their business, the ad likely conveys that the president has knowledge superior to that of ordinary consumers. Accordingly, the president's statement will be deemed to be an expert endorsement. The service must, of course, actually use the endorsed cleanser. In addition, because the advertisement implies that the cleaning service has experience with a reasonable number of leading competitors' brands available to consumers, the service must, in fact, have such experience, and have determined, based on its expertise, that the endorsed product's cleaning ability is at least equal (or superior, if such is the net impression conveyed by the advertisement) to that of the leading competitors' products available to consumers. Because in this example the cleaning service's president makes no mention that the endorsed cleanser was ''chosen,'' ''selected,'' or otherwise evaluated in side-by-side comparisons against its competitors, it is sufficient if the service has relied solely upon its accumulated experience in evaluating cleansers without having performed side-by-side or scientific comparisons.

(6) *Example 6.* A medical doctor states in an advertisement for a drug that the product will safely allow consumers to lower their cholesterol by 50 points. If the materials the doctor reviewed were merely letters from satisfied consumers or the results of a rodent study, the endorsement would likely be deceptive because those materials are not the type of scientific evidence that others with the purported degree of expertise would consider adequate to support this conclusion about the product's safety and efficacy. Under such circumstances, both the advertiser and the doctor would be liable for the doctor's misleading representation (*See* § 255.1(d) and (e)).

§ 255.4 Endorsements by organizations.

Endorsements by organizations, especially expert ones, are viewed as representing the judgment of a group whose collective experience exceeds that of any individual member, and whose judgments are generally free of the sort of subjective factors that vary from individual to individual. Therefore, an organization's endorsement must be reached by a process sufficient to ensure that the endorsement fairly reflects the collective judgment of the organization. Moreover, if an organization is represented as being expert, then, in conjunction with a proper exercise of its expertise in evaluating the product under § 255.3, it must utilize an expert or experts recognized as such by the organization or standards previously adopted by the organization and suitable for judging the relevant merits of such products (*see* § 255.1(e) regarding the liability of endorsers).

(a) *Example 1.* A mattress manufacturer advertises that its product is endorsed by a chiropractic association. Because the association would be regarded as expert with respect to judging mattresses, its endorsement must be supported by an evaluation by an expert or experts recognized as such by the organization, or by compliance with standards previously adopted by the organization and aimed at measuring the performance of mattresses in general and not designed with the unique features of the advertised mattress in mind.

(b) *Example 2.* A trampoline manufacturer sets up and operates what appears to be an independent trampoline review website. The site reviews the manufacturer's trampolines, as well as those of competing manufacturers. Because the website falsely appears to be independent, it is deceptive (*see* § 255.5).

(c) *Example 3.* Assume that a third party operates a wireless headphone review website that provides rankings of different manufacturers' wireless headphones from most recommended to least recommended. The website operator accepts money from manufacturers in exchange for higher rankings of their products. Regardless of whether the website makes express claims of objectivity or independence, such paid-for rankings are deceptive. A headphone manufacturer who pays for a higher ranking on the website may also be held liable for the deception. A disclosure that the website operator receives payments from headphone manufacturers would be inadequate because the payments actually determine the headphones' relative rankings. If, however, the review website does not take payments for higher rankings, but receives payments from some of the headphone manufacturers, such as for affiliate link referrals, it should clearly and conspicuously disclose that it receives such payments (*see* § 255.5(k)(11)).

§ 255.5 Disclosure of material connections.

When there exists a connection between the endorser and the seller of the advertised product that might materially affect the weight or credibility of the endorsement and that connection is not reasonably expected by the audience, such connection must be disclosed clearly and conspicuously. Material connections can include a business, family, or personal relationship. They can include monetary payment or the provision of free or discounted products or services (including products or services unrelated to the endorsed product) to an endorser, regardless of whether the advertiser requires an endorsement in return. Material connections can also include other benefits to the endorser, such as early access to a product or the possibility of being paid, of winning a prize, or of appearing on television or in other media promotions. Some connections may be immaterial because they are too insignificant to affect the weight or credibility given to endorsements. Material connections do not need to be disclosed when they are understood or expected by all but an insignificant portion of the audience for an endorsement. A disclosure of a material connection does not require the complete details of the connection, but it must clearly communicate the nature of the connection sufficiently for consumers to evaluate its significance. Additional guidance is provided by the examples in paragraphs (a) through (l) of this section.

(a) *Example 1.* A drug company commissions research on its product by an outside organization. The drug company determines the overall subject of the research (*e.g.,* to test the efficacy of a newly developed product) and pays a substantial share of the expenses of the research project, but the research organization determines the protocol for the study and is responsible for conducting it. A subsequent advertisement by the drug company mentions the research results as the ''findings'' of that research organization. Although the design and conduct of the

research project are controlled by the outside research organization, the weight consumers place on the reported results could be materially affected by knowing that the advertiser had funded the project. Therefore, the advertiser's payment of expenses to the research organization should be disclosed in the advertisement.

(b) *Example 2.* A film star endorses a particular food product in a television commercial. The endorsement regards only points of taste and individual preference. This endorsement must, of course, comply with § 255.1; but, regardless of whether the star's compensation for the commercial is a $1 million cash payment or a royalty for each product sold by the advertiser during the next year, no disclosure is required because such payments likely are ordinarily expected by viewers.

(c) *Example 3.* (1) During an appearance by a well-known professional tennis player on a television talk show, the host comments that the past few months have been the best of the player's career and during this time the player has risen to their highest level ever in the rankings. The player responds by attributing that improvement to seeing the ball better, ever since having laser vision correction surgery at a specific identified clinic. The athlete continues talking about the ease of the procedure, the kindness of the clinic's doctors, the short recovery time, and now being able to engage in a variety of activities without glasses, including driving at night. The athlete does not disclose having a contractual relationship with the clinic that includes payment for speaking publicly about the surgery. Consumers might not realize that a celebrity discussing a medical procedure in a television interview has been paid for doing so, and knowledge of such payments would likely affect the weight or credibility consumers give to the celebrity's endorsement. Without a clear and conspicuous disclosure during the interview that the athlete has been engaged as a spokesperson for the clinic, this endorsement is likely to be deceptive. A disclosure during the show's closing credits would not be clear and conspicuous. Furthermore, if consumers are likely to take away from the interview that the athlete's experience is typical of those who undergo the same procedure at the clinic, the advertiser must have substantiation for that claim.

(2) Assume that the tennis player also touts the results of the surgery—mentioning the clinic by name—in a social media post. Consumers might not realize that the athlete is a paid endorser and, because that information might affect the weight consumers give to the tennis player's endorsement, the relationship with the clinic should be disclosed—regardless of whether it paid the athlete for that particular post. It should be disclosed even if the relationship involves no payments but only the tennis player getting the laser correction surgery for free or at a reduced cost.

(3) Assume that the clinic uses the tennis player's endorsement in its own social media posts. The clinic should clearly and conspicuously disclose its relationship to the athlete in its posts.

(4) Assume that during the appearance on the television talk show, the tennis player is wearing clothes bearing the insignia of an athletic wear company with which the athlete also has an endorsement contract. Although this contract requires wearing the company's clothes not only on the court but also in public appearances, when possible, the athlete does not mention the clothes or the company during the appearance on the show. No disclosure is required because no representation is being made about the clothes in this context.

(d) *Example 4.* (1) A television ad for an anti-snoring product features a physician who says, ''I have seen dozens of products come on the market over the years and, in my opinion, this is the best ever.'' Consumers would expect the physician to be reasonably compensated for appearing in the ad. Consumers are unlikely, however, to expect that an expert endorser like the physician receives a percentage of gross product sales or owns part of the company, and either of these facts would likely materially affect the credibility that consumers attach to the endorsement. Accordingly, the advertisement should clearly and conspicuously disclose such a connection between the company and the physician.

(2) Assume that the physician is also paid to post about the product on social media, a context in which consumers might not expect that the physician was compensated and more likely to expect that the physician is expressing an independent, professional opinion. Accordingly, the post should clearly and conspicuously disclose the doctor's connection with the company.

(e) *Example 5.* (1) In a television advertisement, an actual patron of a restaurant, who is neither known to the public nor presented as an expert, is shown seated at the counter. The diner is asked for a ''spontaneous'' opinion of a new food product served in the restaurant. Assume, first, that the advertiser had posted a sign on the door of the restaurant informing all who entered that day that patrons would be interviewed by the advertiser as part of its television promotion of its new ''meat-alternative'' burger. A patron seeing such a sign might be more inclined to give a positive review of that item in order to appear on television. The advertisement should thus clearly and conspicuously inform viewers that the patrons on screen knew in advance that they might appear in a television advertisement if they gave the burger a good review because that information may materially affect the weight or credibility of the endorsement.

(2) Assume, in the alternative, that the advertiser had not posted the sign and that patrons asked for their opinions about the burger did not know or have reason to believe until after their response that they were being recorded for use in an advertisement. No disclosure is required here, even if patrons were also told, after the interview, that they would be paid for allowing the use of their opinions in advertising.

(f) *Example 6.* (1) An infomercial producer wants to include consumer endorsements in an infomercial for an automotive additive product not yet on the market. The producer's staff selects several people who work as ''extras'' in commercials and asks them to use the product and report back, telling them that they will be paid a small amount if selected to endorse the product in the infomercial. Viewers would not expect that these ''consumer endorsers'' are actors who used the product in the hope of appearing in the commercial and receiving compensation. Because the advertisement fails to disclose these facts, it is deceptive.

(2) Assume that the additive's marketer wants to have more consumer reviews appear on its retail website which sells a variety of its automotive products. The marketer recruits ordinary consumers to get a free product (*e.g.,* a set of jumper cables or a portable air compressor for car tires) and a $30 payment in exchange for posting a consumer review of the free product on the marketer's website. The marketer makes clear and the reviewers understand that they are free to write negative reviews and that there are no negative consequences of doing so. Any resulting review that fails to clearly and conspicuously disclose the incentives provided to that reviewer is likely deceptive (When the resulting reviews must be positive or reviewers believe they might face negative consequences from posting negative reviews, a disclosure would be insufficient, see

§ 255.2(d) and (e)(9)). Even if adequate disclosures appear in each incentivized review, the practice could still be deceptive if the solicited reviews contain star ratings that are included in an average star rating for the product and including the incentivized reviews materially increases that average star rating.

(g) *Example 7.* A woodworking influencer posts on-demand videos of various projects. A tool manufacturer sends the influencer an expensive full-size lathe in the hope that the influencer would post about it. The woodworker uses the lathe for several products and comments favorably about it in videos. If a significant proportion of viewers are likely unaware that the influencer received the lathe free of charge, the woodworker should clearly and conspicuously disclose receiving it for free, a fact that could affect the credibility that viewers attach to the endorsements. The manufacturer should advise the woodworker at the time it provides the lathe that this connection should be disclosed, and it should have reasonable procedures in place to monitor the influencer's postings for compliance and follow those procedures (*see* § 255.1(d)).

(h) *Example 8.* An online community has a section dedicated to discussions of robotic products. Community members ask and answer questions and otherwise exchange information and opinions about robotic products and developments. Unbeknownst to this community, an employee of a leading home robot manufacturer has been posting messages on the discussion board promoting the manufacturer's new product. Knowledge of this poster's employment likely would affect the weight or credibility of the endorsements. Therefore, the poster should clearly and conspicuously disclose their relationship to the manufacturer to community members. To limit its own liability for such posts, the employer should be engaged in appropriate training of employees. To the extent that the employer has directed such endorsements or otherwise has reason to know about them, it should also be monitoring them and taking other steps to ensure compliance (*see* § 255.1(d)). The disclosure requirements in this example would apply equally to consumer reviews of the product posted on retail websites or review platforms.

(i) *Example 9.* A college student signs up to be part of a program in which points are awarded each time a participant posts on social media about a particular advertiser's products. Participants can then exchange their points for prizes, such as concert tickets or electronics. These incentives would materially affect the weight or credibility of the college student's endorsements. They should be clearly and conspicuously disclosed, and the advertiser should take steps to ensure that these disclosures are being provided.

(j) *Example 10.* Great Paper Company sells photocopy paper with packaging that has a seal of approval from the No Chlorine Products Association, a non-profit third-party association. Great Paper Company paid the No Chlorine Products Association a reasonable fee for the evaluation of its product and its manufacturing process. Consumers would reasonably expect that marketers have to pay for this kind of certification. Therefore, there is no unexpected material connection between the company and the association, and the use of the seal without disclosure of the fee paid to the association would not be deceptive.

(k) *Example 11.* A coffee lover creates a blog that reviews coffee makers. The blogger writes the content independently of the marketers of the coffee makers, but includes affiliate links to websites on which consumers can buy these products from their marketers. Whenever a consumer clicks on such a link and buys the product, the blogger receives a small portion of the sale. Because knowledge of this compensation could affect the weight or credibility site visitors give to the blogger's reviews, the reviews should clearly and conspicuously disclose the compensation.

(l) *Example 12.* (1) Near the beginning of a podcast, the host reads what is obviously a commercial for a product. Even without a statement identifying the advertiser as a sponsor, listeners would likely still expect that the podcaster was compensated, so there is no need for a disclosure of payment for the commercial. Depending upon the language of the commercial, however, the audience may believe that the host is expressing their own views in the commercial, in which case the host would need to hold the views expressed (*see* § 255.0(b)).

(2) Assume that the host also mentions the product in a social media post. The fact that the host did not have to make a disclosure in the podcast has no bearing on whether there has to be a disclosure in the social media post.

§ 255.6 Endorsements directed to children.

Endorsements in advertisements addressed to children may be of special concern because of the character of the audience. Practices which would not ordinarily be questioned in advertisements addressed to adults might be questioned in such cases.

By direction of the Commission.

April J. Tabor,

Secretary.

Note: The following statement will not appear in the Code of Federal Regulations: Statement of Chair Lina M. Khan Regarding the Endorsement Guides Review May 19, 2022.

Today, the Commission is voting on releasing proposed revised ''Guides Concerning Use of Endorsements and Testimonials in Advertising'' and publishing a Notice seeking comment on them (''Revised Guides''). These Guides tell companies how to use endorsements, testimonials, influencers, and consumer reviews in ads without deceiving consumers.

These revisions come at a time when influencer marketing is becoming increasingly prevalent and as consumers increasingly rely on online consumer reviews to decide what to buy. Reports indicate that the global influencer marketing industry is set to grow to approximately $16.4 billion in 2022.[1] Indeed, more than 75% of brand marketers intend to dedicate a budget to influencer marketing in 2022.[2] Influencers who are paid, receive free product or services, or have a relationship with a brand sometimes fail to disclose that material connection, hoping to appear more authentic to consumers. Consumers' increasing reliance on online reviews can also incentivize advertisers to harness fake reviews, suppress negative reviews, and amplify positive ones.

I want to highlight three novel aspects of these Revised Guides that strike me as especially important.

First is the Revised Guides' guidance on platforms' relationships with influencer marketing. Digital platforms profit from influencer marketing and should bear greater responsibility in this area.[3] The Revised Guides warn that some platforms' disclosure tools are inadequate and may expose influencers

[1] Werner Geyser, *The State of Influencer Marketing 2022: Benchmark Report,* Influencer Mktg. Hub (Mar. 2, 2022), *https://influencermarketinghub.com/influencer-marketing-benchmark-report/.*

[2] *Id.* In addition, the global number of influencer marketing related service offerings grew by 26% in 2021 alone, reaching 18,900 firms offering or specializing in influencer marketing services.

[3] Ellen Simon, *How Instagram Makes Money,* Investopedia (March 17, 2022), *https://www.investopedia.com/articles/personal-finance/030915/how-instagram-makes-money.asp* (noting that, in 2019, Instagram generated $20 billion in advertising revenue and that 69% of America's marketers planned to spend most of their 2020 influencer budget on Instagram).

to liability or, in some instances, leave platforms themselves open to liability.

Second is the Revised Guides' explicit guidance on consumer reviews, and specifically the discussion of how encouraging fake reviews and suppressing negative reviews can result in law violations. This guidance reflects recent enforcement actions the agency has taken—including a recent final order settling allegations that Fashion Nova blocked negative reviews of its products from being posted on its website.[4]

Third is the Revised Guides' warning that child-directed influencer advertising is of special concern to the Commission. Those who market to children cannot assume that compliance with these guides is a safe harbor.

The kid influencer marketplace is estimated to be as large as $1.7 billion and is rapidly growing.[5] This type of child-directed influencer advertising can pose a host of risks. As one recent report noted, ''unless children are able to differentiate between advertising and other forms of entertainment, and grasp the persuasive intent of advertising, then they are at risk of deception. This is especially true for children under 12, whose advertising literacy—all knowledge and skills related to understanding advertising—has not yet fully developed.'' [6]

There is currently no clear or consistent approach to addressing the problem, and Congress and advocacy groups have called on the FTC to provide guidance on this issue.[7] While we presently lack the full evidentiary record to support specific guidance or to propose best practices, I am eager for more input that will support more concrete action in this important area. Accordingly, in tandem with issuing the Revised Guides today, we are announcing an event to gather information on stealth advertising targeting children. The public event will be held in October and will focus on the blurring of advertising and programming content in child-directed digital media.

I am eager for robust participation at this event and will look forward to learning from the public as we consider how to move forward on this important and timely issue.

[FR Doc. 2022–12327 Filed 7–25–22; 8:45 am]

BILLING CODE 6750–01–P

[4] Decision and Order, *In re Fashion Nova, LLC,* No. C–4759 (F.T.C. 2022), *https://www.ftc.gov/system/files/ftc_gov/pdf/1923138C4759FashionNovaOrder_0.pdf.*

[5] Agnieszka Guttmann, *Kids Advertising Spending Worldwide 2012–2021, By Format,* Statista (April 7, 2020), *https://www.statista.com/statistics/750865/kids-advertising-spending-worldwide/.*

[6] Miriam Rahali & Sonia Livingstone, #SponsoredAds: Monitoring Influencer Marketing to Young Audiences 8 (2002), *http://eprints.lse.ac.uk/113644/7/Sponsoredads_policy_brief.pdf.*

[7] *See, e.g.,* Letter from Rep. Eshoo, Rep. Castor & Sen. Markey to Joseph J. Simons, Chair, Fed. Trade Comm'n (Aug. 22, 2019), *https://eshoo.house.gov/sites/eshoo.house.gov/files/wysiwyg_uploaded/Eshoo-Markey-Castor%20follow%20up%20letter%20to%20FTC%20re%20predatory%20online%20ads%20%28002%29.pdf*; Letter from Sen. Blumenthal, Sen. Markey, and Rep. Eshoo to Joseph J. Simons, Chair, Fed. Trade Comm'n (Dec. 6, 2019), *https://www.blumenthal.senate.gov/imo/media/doc/2019.12.06%20-%20FTC%20-%20Child%20Influencers.pdf*; Letter from Laura Smith, Legal Director, Truth in Advertising, Inc. & Bonnie Patten, Executive Director, Truth in Advertising, Inc. to Andrew Smith, Director, Bureau of Consumer Prot., Fed. Trade Comm'n & Mary Engle, Associate Director, Div. of Advertising Pracs., Fed. Trade Comm'n (Aug. 28, 2019), *https://truthinadvertising.org/wp-content/uploads/2019/08/8_28_19-ltr-to-FTC-re-Ryan-ToysReview_Redacted.pdf.*

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1240

[CPSC Docket No. CPSC–2020–0010]

Safety Standard for Crib Bumpers/Liners; Withdrawal

AGENCY: Consumer Product Safety Commission.

ACTION: Termination of rulemaking.

SUMMARY: On May 16, 2022, the President signed into law the Safe Sleep for Babies Act of 2021 (SSBA), requiring that crib bumpers, ''regardless of the date of manufacture, shall be considered a banned hazardous product'' under the Consumer Product Safety Act (CPSA). In light of that new statutory direction, CPSC is terminating its pending rulemaking proceeding on crib bumpers/liners, and in a separate notice of proposed rulemaking, proposing to codify the requirements for crib bumpers pursuant to the SSBA. The Commission is also terminating the related proposed rule amendment to include the safety standard for crib bumpers/liners in the list of notice of requirements, as well as the related proposed amendment to identify ''crib bumpers/liners'' as a durable infant or toddler product subject to CPSC's consumer registration requirements.

DATES: The notice of proposed rulemaking published at 85 FR 18878, April 3, 2020, is withdrawn as of July 26, 2022.

ADDRESSES: U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Pamela J. Stone, Attorney Advisor, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7619; email: *pstone@cpsc.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 3 of the Safe Sleep for Babies Act of 2021, H.R. 3182, Public Law 117–126 (SSBA), the Commission is terminating the rulemaking on crib bumpers/liners it commenced under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), CPSC Docket No. CPSC–2020–0010.[1] Under a separate **Federal Register** document, published elsewhere in this issue of the **Federal Register**, CPSC is issuing a proposed rule stating that crib bumpers are banned under the SSBA.

On April 3, 2020, the Commission published a notice of proposed rulemaking (NPR) that set forth proposed requirements for a safety standard for crib bumpers/liners pursuant to section 104 of the CPSIA (85 FR 18878). The Commission received comments on the proposed rule but has not published a final rule.

On May 3, 2022, Congress passed the SSBA, which the President signed on May 16, 2022. Section 3 of the SSBA requires that, not later than 180 days after enactment, ''crib bumpers, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).'' 15 U.S.C. 2057e.

In light of the SSBA's mandate that crib bumpers shall be considered a banned hazardous product under section 8 of the CPSA, CPSC is no longer proposing to regulate crib bumpers under the CPSIA and is terminating that rulemaking to establish a consumer product safety standard for crib bumpers/liners. In a separate **Federal Register** notice, CPSC proposes to issue a rule stating that crib bumpers are banned pursuant to the SSBA's designation of crib bumpers as a banned hazardous product.

The termination of the crib bumpers/liners rulemaking includes termination of the proposal to amend 16 CFR part 1130 to include ''crib bumpers/liners'' in the definition of a ''durable infant or toddler product.'' 85 FR at 18893. The termination of this rulemaking additionally terminates the proposal to issue a notice of requirements for crib bumpers/liners, which proposed to amend 16 CFR part 1112 to include 16 CFR part 1240, the CFR section where the crib bumpers/liners standard would

[1] On July 19, 2022, the Commission voted 5–0 to issue this notice terminating rulemaking.

have been codified if the standard had become final. *Id.*

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–15905 Filed 7–25–22; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1309

[CPSC Docket No. 2022–0024]

Ban of Crib Bumpers

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: On May 16, 2022, the President signed into law the Safe Sleep for Babies Act of 2021, requiring that crib bumpers, ''regardless of the date of manufacture, shall be considered a banned hazardous product'' under the Consumer Product Safety Act (CPSA). Pursuant to this authority, CPSC is proposing to codify the ban on crib bumpers pursuant to the Safe Sleep for Babies Act, and under a separate document, published elsewhere in this issue of the **Federal Register**, terminate the rulemaking on crib bumpers/liners under the Consumer Product Safety Improvement Act of 2008 (CPSIA).

DATES: Submit comments by August 25, 2022.

ADDRESSES: You can submit comments, identified by Docket No. CPSC–2022–0024, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (email), except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/Hand Delivery/Courier Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

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

Docket: To review background documents or comments received on the proposed codification of the Ban on Crib Bumpers, go to: *https://www.regulations.gov,* and insert the docket number, CPSC–2022–0024, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Timothy P. Smith, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301)987–2557; email: *tsmith@cpsc.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 3 of the Safe Sleep for Babies Act of 2021, H.R. 3182, Public Law 117–126 (SSBA), CPSC is issuing a proposed rule to codify the ban on crib bumpers under the SSBA. Additionally, under a separate **Federal Register** document, published elsewhere in this issue of the **Federal Register**, the Commission is terminating the pending rulemaking on crib bumpers/liners that CPSC initiated under section 104 of the CPSIA, CPSC Docket No. CPSC–2020–0010.

I. Background and Statutory Authority

On April 3, 2020, the Commission published a notice of proposed rulemaking (NPR) that set forth proposed requirements for a safety standard for crib bumpers/liners pursuant to section 104 of the CPSIA (85 FR 18878). The Commission received comments on the proposed rule but has not published a final rule.

On May 3, 2022, Congress passed the SSBA, which the President signed on May 16, 2022. Section 3 of the SSBA requires that, not later than 180 days after enactment, ''crib bumpers, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).'' 15 U.S.C. 2057e.

In light of the SSBA's mandate that crib bumpers shall be considered a banned hazardous product under section 8 of the CPSA, CPSC no longer proposes to regulate crib bumpers under the CPSIA. By separate **Federal Register** *document,* CPSC is terminating the rulemaking to establish a consumer product safety standard for crib bumpers/liners.[1] Instead, CPSC now proposes to achieve a similar improvement to safety by codifying the ban on ''crib bumpers,'' as defined in section 3 of the SSBA, as banned hazardous products.[2]

II. Description of Proposed Ban on Crib Bumpers

In this rulemaking, CPSC proposes to codify the SSBA's mandate that ''crib bumpers'' are banned hazardous products, as set forth below.

A. Definitions

The Commission proposes codifying the definition of ''crib bumper'' used in the SSBA, which states that ''crib bumper'':

- Means any material that is intended to cover the sides of a crib to prevent injury to any crib occupant from impacts against the side of a crib or to prevent partial or complete access to any openings in the sides of a crib to prevent a crib occupant from getting any part of the body entrapped in any opening;
- Includes a padded crib bumper, a supported and unsupported vinyl bumper guard, and vertical crib slat covers; and
- Does not include a non-padded mesh crib liner.

B. Effective Date

The SSBA states that crib bumpers shall be considered banned hazardous products ''not later than 180 days after the enactment of this Act,'' *i.e.,* not later than November 12, 2022. Applying the 180-day effective date referenced by Congress would avoid confusion among manufacturers and retailers, while also being consistent with the 6-month implementation period the Commission proposed in its 2020 NPR to establish a safety standard for crib bumpers/liners. Therefore, CPSC proposes to make the effective date for the ban on crib bumpers November 12, 2022.

C. Inventory

The SSBA states that the ban applies to crib bumpers ''regardless of the date of manufacture.'' Therefore, crib bumpers manufactured before the ban

[1] The NPR used the terms ''crib bumpers,'' ''crib bumpers and liners,'' and ''crib bumpers/liners,'' but this NPR applies only to ''crib bumpers'' as defined in the SSBA.

[2] On July 19, 2022, the Commission voted 5–0 to issue this notice of proposed rulemaking.

becomes effective will be banned hazardous products beginning on the effective date of the SSBA, as well as any crib bumpers manufactured or sold after the effective date.

III. Preemption

Section 3(b)(2)(A) of the Executive Order 12988, *Civil Justice Reform* (Feb. 5, 1996), directs agencies to specify the preemptive effect of any rule. 61 FR 4729 (Feb. 7, 1996). Because the SSBA states that crib bumpers are banned hazardous products, any state performance standards for a ''crib bumper,'' as defined in the SSBA (which expressly excludes non-padded mesh crib liners), would be inconsistent with federal law, and therefore, preempted.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses, and identify alternatives that may reduce such impact, unless the agency certifies that the rule if promulgated, will not have a significant economic impact on a substantial number of small entities. The SSBA will take effect no later than November 12, 2022. Because the proposed rule is limited to codifying section 3 of the SSBA, with an effective date of November 12, 2022, the proposed rule imposes no additional economic impact on small entities beyond the requirements of the SSBA itself. Therefore, the Commission certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

V. Environmental Considerations

The Commission's regulations address whether the agency must prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions that have ''little or no potential for affecting the human environment'' do not require an environmental assessment or an environmental impact statement. 16 CFR 1021.5(c). The proposed rule codifying section 3 of the SSBA falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

VI. Paperwork Reduction Act

The proposed rule to codify crib bumpers as a banned hazardous product contains no information collection requirements that would be subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). However, if the Commission requires testing and certification to this ban, the Commission will expand the existing control number for Third Party Testing of Children's Products, OMB Control No. 3041–0159.

VII. Request for Comments

We invite comments on all aspects of the Commission's proposal to codify the ban on crib bumpers in section 3 of the SSBA with an effective date of November 12, 2022. Comments must be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this document. CPSC specifically requests comment on the following:

A. Effective Date: The Commission proposes to implement the crib bumper ban in the SSBA with an effective date of November 12, 2022. Should the Commission adopt this proposed effective date, or an alternative date ''[n]ot later than 180 days after the date of enactment''? If the commenter believes that an effective date later than November 12, 2022, is permitted under section 3 of the SSBA, what is the legal basis for that assertion, and what later date should be adopted?

B. Testing and Certification: When a ban does not remove all products in a product category from the market, testing and certification requirements may apply. For example, CPSC requires a General Certificate of Conformity (GCC) for certain banned hazardous products. *See, e.g., https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Lab-Accreditation/Rules-Requiring-a-General-Certificate-of-Conformity,* CPSC's website providing guidance that bans set forth in 16 CFR parts 1304, 1305, and 1306 require a GCC. In this case, non-padded mesh crib liners are not within the scope of the SSBA's ban on crib bumpers. Because the crib bumper ban does not eliminate non-padded mesh crib liners from the market, what, if any, testing and certification requirements remain? For example, should CPSC require certification to the ban for non-padded mesh crib liners to demonstrate that a product is *not* within the scope of the ban? Why, or why not? Additionally, should the Commission add ''non-padded mesh crib liners'' to the list of durable infant or toddler products that require a registration card? Why, or why not?

List of Subjects in 16 CFR Part 1309

Administrative practice and procedure, Consumer protection, Infants and children.

For the reasons stated in the preamble, the Commission proposes to add part 1309 to title 16 of the Code of Federal Regulations to read as follows:

PART 1309—BAN OF CRIB BUMPERS

Sec.
1309.1 Purpose and scope.
1309.2 Definitions.
1309.3 Banned hazardous product.
1309.4 Effective date.

Authority: Sec. 3, Pub. L. 117–126, 136 Stat. 1208. 15 U.S.C. 2057e.

§ 1309.1 Purpose and scope.

The purpose of this part is to prohibit the sale of crib bumpers, as defined in § 1309.2, as set forth in the Safe Sleep for Babies Act of 2021.

§ 1309.2 Definitions.

Crib bumper, as used in this part:

a. Means any material that is intended to cover the sides of a crib to prevent injury to any crib occupant from impacts against the side of a crib or to prevent partial or complete access to any openings in the sides of a crib to prevent a crib occupant from getting any part of the body entrapped in any opening;

b. Includes a padded crib bumper, a supported and unsupported vinyl bumper guard, and vertical crib slat covers; and

c. Does not include a non-padded mesh crib liner.

§ 1309.3 Banned hazardous product.

Any crib bumper, as defined in section 1309.2, regardless of the date of manufacture, is a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).

§ 1309.4 Effective date.

The effective date of this ban is November 12, 2022.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–15906 Filed 7–25–22; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1310

[CPSC Docket No. 2022–0025]

Ban of Inclined Sleepers for Infants

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: On May 16, 2022, the President signed into law the Safe Sleep for Babies Act of 2021 (SSBA), requiring that ''inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product'' under the Consumer Product Safety Act (CPSA). Pursuant to this authority, the U.S. Consumer Product Safety Commission (CPSC, or Commission) is proposing to codify the ban on inclined sleepers for infants.

DATES: Submit comments by August 25, 2022.

ADDRESSES: You can submit comments, identified by Docket No. CPSC–2020–0025, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (email), except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/Hand Delivery/Courier Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

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

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov,* and insert the docket number, CPSC–2020–0025f, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Celestine T. Kish, Project Manager, Directorate for Engineering, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2547; email: *ckish@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

On May 3, 2022, Congress passed the Safe Sleep for Babies Act of 2021, H.R. 3182, Public Law 117–126, which the President signed on May 16, 2022. Section 2(a) of the SSBA requires that, not later than 180 days after enactment, ''inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).'' 15 U.S.C. 2057d(a).

II. Description of Proposed Ban on Inclined Infant Sleepers

In this rulemaking, CPSC proposes to codify the SSBA's mandate that ''inclined sleepers for infants'' are a banned hazardous product, as set forth below.[1]

A. Definitions

The Commission proposes codifying the definition of ''inclined sleepers for infants'' as stated in section 2(b) the SSBA: ''a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.''

B. Effective Date

Section 2(a) of the SSBA states that inclined sleepers for infants shall be considered a banned hazardous product ''not later than 180 days after the enactment of this Act,'' *i.e.,* not later than November 12, 2022. CPSC proposes to make the effective date for this ban November 12, 2022, consistent with 180-day period referenced by Congress.

C. Inventory

The SSBA states that the ban applies to inclined sleepers for infants as defined in section 2 ''regardless of the date of manufacture.'' Therefore, inclined sleepers for infants manufactured before the ban becomes effective will be banned hazardous products beginning on the effective date, as well as any inclined sleepers for infants manufactured or sold on or after the effective date.

III. Preemption

Section 3(b)(2)(A) of Executive Order 12988, *Civil Justice Reform* (Feb. 5, 1996), directs agencies to specify the preemptive effect of any rule. 61 FR 4729 (Feb. 7, 1996). Because the SSBA states that inclined sleepers for infants are banned hazardous products, any state performance standards for inclined sleepers for infants, as those products are defined in the SSBA, would be inconsistent with federal law and therefore preempted by this ban.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses, and identify alternatives that may reduce such impact, unless the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The SSBA will take effect on November 12, 2022. Because the proposed rule would adopt the same effective date and is limited to codifying the relevant provisions of the SSBA with regard to inclined sleepers for infants, the proposed rule imposes no additional economic impact on small entities beyond the requirements of section 2 of the SSBA. Therefore, the Commission certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

V. Environmental Considerations

The Commission's regulations address whether the agency must prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions that have ''little or no potential for affecting the human environment'' do not require an environmental assessment or an environmental impact statement. 16 CFR 1021.5(c). The proposed rule codifying section 2 of the SSBA falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

[1] On July 19, 2022, the Commission voted 5–0 to issue this notice of proposed rulemaking.

VI. Paperwork Reduction Act

The proposed rule to codify inclined sleepers for infants as a banned hazardous product contains no information collection requirements that would be subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). However, if the Commission requires testing and certification to this ban, the Commission will expand the existing control number for Third Party Testing of Children's Products, OMB Control No. 3041–0159.

VII. Request for Comments

We invite comments on all aspects of the Commission's proposal to codify the ban on inclined sleepers for infants under section 2 of the SSBA with an effective date of November 12, 2022. Comments must be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice. We also invite comment on the following topics:

A. Effective Date: The Commission proposes to implement the inclined sleeper ban in the SSBA with an effective date of November 12, 2022. Should the Commission adopt this proposed effective date, or an alternative date ''[n]ot later than 180 days after the date of enactment''? If the commenter believes that an effective date later than November 12, 2022, is permitted under section 2 of the SSBA, what is the legal basis for that assertion, and what later date should be adopted?

B. Interpretation: In 2021, the Commission promulgated its Safety Standard for Infant Sleep Products (16 CFR part 1236, the ISP Rule), which became effective on June 23, 2022. (86 FR 33022 (June 23, 2021)). Pursuant to 16 CFR 1236.2(b)(10)(i), the ISP Rule defines an ''infant sleep product'' as a ''product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that is not subject to'' one of the following: 16 CFR part 1218 (bassinets and cradles); 16 CFR part 1219 (full-size cribs); 16 CFR part 1220 (non-full-size cribs); 16 CFR part 1221 (play yards); and 16 CFR part 1222 (bedside sleepers) (collectively, CPSC sleep standards).[2] 86 FR at 33072. The SSBA, by contrast, applies to products ''marketed, intended, or designed'' for infants up to 1 years old. The operative provisions of the SSBA and the ISP Rule thus are not identical. Particularly in that light, the Commission requests comment on interpreting, codifying, and enforcing the SSBA with respect to inclined sleep products, including:

1. How should the Commission interpret and implement the phrase ''sleeping accommodations'' for purposes of the SSBA ban?
2. What, if any, effect should inclusion of the term ''designed'' in the SSBA have on the Commission's interpretation and implementation of the SSBA as compared to the ISP Rule? For example, what significance, if any, might ''designed'' have for inclined products that are not marketed for sleep but in which an infant may fall asleep, such as bouncers, swings, and rockers?
3. In the SSBA, what product characteristics, if any, demonstrate that a product is ''designed'' for sleep?
4. How should the Commission interpret and implement the terms ''marketed'' and ''intended'' as a sleeping accommodation in the SSBA? Should these terms be interpreted and implemented the same as in the ISP Rule? Why or why not?
5. What is the significance of the age distinction between the ISP Rule and the SSBA's ban? How might this difference bear on implementation of the SSBA as compared to the ISP Rule, including with respect to developmental differences between a newborn to 5 month old as identified in the ISP Rule, versus a newborn to 1 year old as identified in the SSBA?
6. How, if at all, should the SSBA's ban of inclined sleepers for infants affect the ISP Rule or the Commission's application of it?

C. Testing and Certification: When a ban does not remove all products in a product category from the market, testing and certification requirements may apply. For example, CPSC requires a General Certificate of Conformity (GCC) for certain banned hazardous products. *See, e.g., https://www.cpsc.gov/Business-Manufacturing/Testing-Certification/Lab-Accreditation/Rules-Requiring-a-General-Certificate-of-Conformity,* CPSC's website providing guidance that bans set forth in 16 CFR parts 1304, 1305, and 1306 require a GCC. In this case, inclined sleepers with an inclined sleep surface of 10 degrees or less, or that are marketed, intended, or designed to provide sleeping accommodations for an infant older than 1 year, are not within the scope of the SSBA's ban. To the extent inclined sleepers remain on the market that are not banned by this rule, and that are not regulated under the ISP Rule, should CPSC require testing and certification to this ban, to demonstrate that a product is *not* within the scope of the ban? Why, or why not?

[2] If an infant sleep product does not already comply with a CPSC sleep standard, the ISP Rule requires the sleep surface angle to measure l0 degrees or less, and the product must meet part 1218 of the Commission's Rules, the bassinet standard, including the definition of a bassinet, meaning the product must have a stand. The ISP Rule applies to both flat and inclined products.

List of Subjects in 16 CFR Part 1310

Administrative practice and procedure, Consumer protection, Infants and children.

For the reasons stated in the preamble, the Commission proposes to add part 1310 to title 16 of the Code of Federal Regulations as follows:

PART 1310—BAN OF INCLINED SLEEPERS FOR INFANTS

Sec.
1310.1 Purpose and scope
1310.2 Definition
1310.3 Banned hazardous product
1310.4 Effective date

Authority: Sec. 2, Pub. L. 117–126, 136 Stat. 1208; 15 U.S.C. 2057d.

§ 1310.1 Purpose and scope

The purpose of this rule is to prohibit the sale of inclined sleepers for infants as set forth in the Safe Sleep for Babies Act of 2021.

§ 1310.2 Definition

Inclined sleeper for infants means ''a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.''

§ 1310.3 Banned Hazardous product

Any inclined sleeper for infants, regardless of the date of manufacture, is a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).

§ 1310.4 Effective date

The effective date of this ban is November 12, 2022.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–15904 Filed 7–25–22; 8:45 am]

BILLING CODE 6355–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0092; FRL–10017–01–R4]

Air Plan Approval; Kentucky; Emissions Inventory Requirements for the 2015 8-Hour Ozone Standard Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Kentucky, through the Kentucky Energy and Environment Cabinet (Cabinet) on December 22, 2021, to address the base year emissions inventory requirements for the 2015 8-hour ozone national ambient air quality standard (NAAQS) for Kentucky counties in the Cincinnati, Ohio-Kentucky 2015 8-hour ozone NAAQS nonattainment area (hereinafter referred to as the Cincinnati, OH-KY Area), and for Kentucky counties in the Louisville, Kentucky-Indiana 2015 8-hour NAAQS nonattainment area (hereinafter referred to as the Louisville, KY-IN Area). Specifically, EPA is proposing to approve Kentucky's SIP revision addressing the emissions inventory requirements for the 2015 8-hour ozone nonattainment areas for the portions of Boone, Campbell, and Kenton Counties in the Cincinnati, OH-KY Area, and Bullitt, Jefferson, and Oldham Counties in the Louisville, KY-IN Area. These requirements apply to all ozone nonattainment areas. This action is being proposed pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before August 25, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2022–0092 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Sarah LaRocca, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8994. Ms. LaRocca can also be reached via electronic mail at *larocca.sarah@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 1, 2015, EPA promulgated a revised 8-hour primary and secondary ozone NAAQS, strengthening both from 0.075 parts per million (ppm) to 0.070 ppm (the 2015 8-hour ozone NAAQS). *See* 80 FR 65292 (October 26, 2015). The 2015 8-hour ozone NAAQS is set at 0.070 ppm based on an annual fourth-highest daily maximum 8-hour average concentration averaged over three years. Under EPA's regulations at 40 Code of Federal Regulations (CFR) part 50, the 2015 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ambient air quality ozone concentration is less than or equal to 0.070 ppm. *See* 40 CFR 50.19. Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. *See* 40 CFR part 50, Appendix U. The ambient air quality monitoring data completeness requirement is met when the average percentage of days with valid ambient monitoring data is greater than 90 percent and no single year has less than 75 percent data completeness as determined using Appendix U.

Upon promulgation of a new or revised ozone NAAQS, the CAA requires EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data. On June 4, 2018 (effective August 3, 2018), EPA designated the 7-county Cincinnati, OH-KY Area as a Marginal ozone nonattainment for the 2015 8-hour ozone NAAQS.[1] *See* 83 FR 25776. Also, on June 4, 2018 (effective August 3, 2018), EPA designated the five-county Louisville, KY-IN Area as a Marginal ozone nonattainment for the 2015 8-hour ozone NAAQS.[2] The Cincinnati, OH-KY Area and the Louisville, KY-IN Area were designated nonattainment for the 2015 8-hour ozone NAAQS using 2014–2016 ambient air quality data.

On December 6, 2018, EPA finalized a rule titled ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements'' (SIP Requirements Rule) that establishes the requirements that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where air quality exceeds the 2015 8-hour ozone NAAQS.[3] *See* 83 FR 62998; 40 CFR part 51, subpart CC. This rule establishes nonattainment area attainment deadlines based on Table 1 of section 181(a) of the CAA, including an attainment deadline of August 3, 2021, three years after the August 3, 2018, effective date, for areas classified as Marginal for the 2015 8-hour ozone NAAQS.

Ground level ozone is not emitted directly into the air but is created by chemical reactions between oxides of nitrogen (NO_X) and volatile organic compounds (VOC) in the presence of sunlight. Emissions from industrial facilities and electric utilities, motor vehicle exhaust, gasoline vapors, and chemical solvents are some of the major sources of NO_X and VOC. Section 182(a)(1) of the CAA requires states with areas designated nonattainment for the ozone NAAQS to submit a SIP revision providing a comprehensive, accurate, and current inventory of actual emissions from all sources of the relevant pollutant or pollutants in such area. NO_X and VOC are the relevant pollutants because they are the precursors—*i.e.,* the pollutants that contribute to the formation—of ozone.

Based on the nonattainment designation, Kentucky was required to develop a SIP revision addressing certain CAA requirements for the Cincinnati, OH-KY Area and the Louisville, KY-IN Area. Among other things, Kentucky was required to submit a SIP revision addressing the emissions inventory requirements in CAA section 182(a)(1).

[1] The Cincinnati, OH-KY Area consists of the following counties: Boone (partial), Campbell (partial), and Kenton (partial) in Kentucky and the entire counties of Butler, Clermont, Hamilton, and Warren in Ohio. EPA took action on the 2015 8-hour ozone NAAQS nonattainment area emissions inventory requirements for Butler, Clermont, Hamilton, and Warren Counties in Ohio in a separate action. *See* 86 FR 12270 (March 3, 2021).

[2] The Louisville, KY-IN Area consists of Bullitt, Jefferson, and Oldham Counties in Kentucky and Clark and Floyd Counties in Indiana. EPA took action on the 2015 8-hour ozone NAAQS nonattainment area emissions inventory requirements for Clark and Floyd Counties in Indiana in a separate action. *See* 87 FR 39750 (July 5, 2022).

[3] The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2015 8-hour ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology, reasonably available control measures, major nonattainment new source review, emission inventories, and the timing of SIP submissions and compliance with emission control measures in the SIP.

II. Commonwealth's Submittal

On December 22, 2021, Kentucky submitted a SIP revision addressing the emissions inventory requirements related to the 2015 8-hour ozone NAAQS for the Cincinnati, OH-KY Area and the Louisville, KY-IN Area.[4] EPA is proposing to approve this SIP revision as meeting the inventory requirements of section 182(a)(1) of the CAA and EPA's SIP Requirements Rule. More information on EPA's analysis of Kentucky's SIP revision and how this SIP revision addresses these requirements is provided below.

III. Analysis of Commonwealth's Submittal

As discussed above, section 182(a)(1) of the CAA requires areas to submit a comprehensive, accurate, and current inventory of actual emissions from all sources of the relevant pollutant or pollutants in each ozone nonattainment area. The section 182(a)(1) base year inventory is defined in the SIP Requirements Rule as ''a comprehensive, accurate, current inventory of actual emissions from sources of VOC and NO_X emitted within the boundaries of the nonattainment area as required by CAA section 182(a)(1).'' *See* 40 CFR 51.1300(p). The inventory year must be selected consistent with the baseline year for the RFP plan as required by 40 CFR 51.1310(b),[5] and the inventory must include actual ozone season day emissions as defined in 40 CFR 51.1300(q)[6] and contain data elements consistent with the detail required by 40 CFR part 51, subpart A. *See* 40 CFR 51.1315(a), (c), and (e). In addition, the point source emissions included in the inventory must be reported according to the point source emissions thresholds of the Air Emissions Reporting Requirements (AERR) in 40 CFR part 51, subpart A.

Kentucky selected 2017 as the base year for the emissions inventories, which is the most recent calendar year for which a complete triennial inventory is required to be submitted to the EPA under 40 CFR part 51, subpart A. This base year is consistent with the regulations for 2015 ozone NAAQS nonattainment area base year emission inventory regulations. *See* 40 CFR 51.1315(a) and 51.1310(b). The emissions inventory is based on data developed and submitted by both the Cabinet and Louisville Metro Air Pollution Control District (District)[7] to EPA's 2017 National Emissions Inventory (NEI), and it contains data elements consistent with the requirements of 40 CFR part 51, subpart A.

Kentucky's emissions inventory for the Cincinnati, OH-KY Area and Louisville, KY-IN Area provides 2017 typical average summer day emissions for NO_X and VOC for the following general source categories: point sources, nonpoint sources,[8] on-road mobile sources, and non-road. For the Kentucky portion of the Cincinnati, OH-KY Area, the following percentages represent the portions of each Kentucky county that are located in the Area: Boone: 95 percent; Campbell: 92 percent; and Kenton: 95 percent. The nonattainment area apportionment percentages were applied to the point, nonpoint, and nonroad sectors. For on-road emissions, vehicle miles traveled (VMT) data for the nonattainment portions of the counties were used as inputs to the MOVES 3 model. Annual emission totals were then converted to tons per summer day by taking the calculated annual emissions totals, multiplying them by 25 percent to account for the four seasons, and then dividing by the 92 days of the summer season.[9] For the Kentucky portion of the Louisville, KY-IN Area, summer day emissions were calculated using a ''Summer's Operation Percentage'' as reported by facilities and explained in Appendices E.2 and A.3 of the submittal. Table 1 and Table 2 provide a summary of the emissions inventories for the Kentucky portions of the Cincinnati, OH-KY Area and the Louisville, KY-IN Area, respectively.

[4] On October 15, 2020, the Cabinet submitted a certification that included other required elements for ozone nonattainment areas pursuant to CAA section 182(a)(2)(C), Nonattainment New Source Review, and CAA section 182(a)(3)(B), Emissions statements. On August 12, 2020, KDAQ submitted a certification on behalf of the Louisville Metro Air Pollution Control District that included the required elements for ozone nonattainment areas pursuant to CAA section 182(a)(3)(B), Emissions statements. On April 5, 2022, EPA took final action on the portion of Kentucky's October 15, 2020, submission related to CAA section 182(a)(2)(C), Nonattainment New Source Review. *See* 87 FR 19649. On March 9, 2022, EPA took final action on the District's August 12, 2020, submission related to CAA section 182(a)(3)(B), Emissions statements. *See* 87 FR 13177. On April 26, 2022, EPA took final action on the portion of Kentucky's October 15, 2020, submission related to CAA section 182(a)(3)(B), Emissions statements. *See* 87 FR 24429.

[5] 40 CFR 51.1310(b) states that ''at the time of designation for the ozone NAAQS the baseline emissions inventory shall be the emissions inventory for the most recent calendar year for which a complete triennial inventory is required to be submitted to the EPA under the provisions of subpart A of this part. States may use an alternative baseline emissions inventory provided that the year selected corresponds with the year of the effective date of designation as nonattainment for that NAAQS. All states associated with a multi-state nonattainment area must consult and agree on using the alternative baseline year. The emissions values included in the inventory required by this section shall be actual ozone season day emissions . . . .'' For additional information, please see the guidance document titled ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations,'' EPA–454/B–17–003, July 2017, available at: *https://www.epa.gov/air-emissions-inventories/air-emissions-inventory-guidance-implementation-ozone-and-particulate.*

[6] ''Ozone season day emissions'' is defined as ''an average day's emissions for a typical ozone season work weekday. The state shall select, subject to EPA approval, the particular month(s) in the ozone season and the day(s) in the work week to be represented, considering the conditions assumed in the development of RFP plans and/or emissions budgets for transportation conformity.'' *See* 40 CFR 51.1300(q).

[7] The Cabinet submitted emissions inventories for the KY portion of both the Cincinnati, OH-KY and the Louisville, KY-IN nonattainment areas for the 2015 8-hour ozone standard. The District provided emissions information for the Jefferson County portion of the Louisville, KY-IN nonattainment area for the 2015 8-hour ozone standard.

[8] On June 2, 2022, Kentucky informed EPA that the Base Year (Nonattainment) Emissions Inventory State Implementation Plan it submitted on December 22, 2021, included biogenic emissions in the nonpoint category, whereas biogenic emissions were excluded from the inventories developed for Kentucky's redesignation requests and maintenance plans for the Cincinnati and Louisville Areas, in accordance with EPA Guidance (*Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations* (May 2017)). Kentucky's June 2, 2022, email is included in the docket for this proposed action.

[9] For sources that reported seasonal operations (primarily in Jefferson County), the seasonal operations data was used to calculate summer emissions, which were then divided by the 92 days in the summer months (June, July, and August) to derive tons per ozone season day/tons per summer day emissions. For the remaining sources, tons per summer day emissions were calculated by dividing annual emissions by four and then by the 92 days of summer. EPA has preliminarily determined that this is an appropriate method for determining summer day emissions, as the average summer operations from facilities reporting such information were determined to be approximately 24.6% to 26.3% (approximately 25%) of the annual emissions. Furthermore, for one of the largest contributors to these remaining emissions, the Louisville International Airport, this method of approximation is supported by data available on monthly flights indicating that flights in June, July, and August made up almost precisely one quarter of total annual flights (25.1%).

TABLE 1—2017 EMISSIONS FOR THE KENTUCKY PORTION OF THE CINCINNATI, OH-KY AREA

[Tons/summer day]

County	Point		Nonpoint		On-road		Non-road	
	NO_X	VOC	NO_X	VOC	NO_X	VOC	NO_X	VOC
Boone	9.47	2.57	1.60	14.78	3.78	2.31	0.67	1.20
Campbell	0.32	0.41	1.08	6.46	1.78	1.08	0.34	0.37
Kenton	0.30	0.66	1.82	7.43	3.77	2.12	0.58	0.65

TABLE 2—2017 EMISSIONS FOR THE KENTUCKY PORTION OF THE LOUISVILLE, KY-IN AREA

[Tons/summer day]

County	Point		Nonpoint		On-road		Non-road	
	NO_X	VOC	NO_X	VOC	NO_X	VOC	NO_X	VOC
Bullitt	0.85	9.33	0.84	18.13	3.49	1.19	0.26	0.42
Jefferson	34.81	21.56	6.66	41.57	20.97	7.85	4.32	4.02
Oldham	0.13	0.04	0.87	5.98	1.85	0.69	0.30	0.41

The emissions reported for the Cincinnati, OH-KY Area and for the Louisville, KY-IN Area reflect the emissions within the portions of Boone, Campbell, and Kenton Counties, and within Bullitt, Jefferson, and Oldham Counties, respectively, comprising the nonattainment areas. The inventory contains point source emissions data for facilities located within the Kentucky portions of the Areas. More detail on the emissions for individual source categories is provided below and in the appendices to Kentucky's December 22, 2021, submittal.

Point sources are large, stationary, identifiable sources of emissions that release pollutants into the atmosphere. NO_X and VOC emissions were calculated by using facility-specific emissions data reported to the 2017 NEI from sources that are required to submit inventory data according to the AERR. A detailed account of the point source emissions can be found in Appendix A of Kentucky's submittal.

Nonpoint sources are small stationary sources of emissions, which due to their large number, collectively have significant emissions (*e.g.,* dry cleaners, service stations). Emissions for these sources were obtained from the 2017 NEI. A detailed account of the nonpoint source emissions can be found in Appendix B of Kentucky's submittal.

On-road mobile sources include vehicles used on roads for transportation of passengers or freight. For both the Cincinnati, OH-KY Area and Louisville, KY-IN Area, on-road emissions inventories were developed using the latest version of EPA's Motor Vehicle Emissions Simulator (MOVES), MOVES3, for each ozone nonattainment county. County level on-road emissions modeling was conducted using county-specific vehicle populations and other local data. A detailed account of the on-road source emissions can be found on page 6, page 12, and in Appendix C of Kentucky's submittal.

Non-road mobile sources include vehicles, engines, and equipment used for construction, agriculture, recreation, and other purposes that do not use the roadways (*e.g.,* lawn mowers, construction equipment, railroad locomotives, and aircraft). Kentucky obtained emissions for the non-road mobile sources from the 2017 NEI. A detailed account of non-road mobile source emissions can be found in Appendix D of the December 22, 2021, submittal.

EPA has preliminarily determined that Kentucky's emissions inventories for the Cincinnati, OH-KY and the Louisville, KY-IN Areas meet the requirements under CAA section 182(a)(1) and the SIP Requirements Rule for the 2015 8-hour ozone NAAQS, as well as the requirements in 40 CFR part 51, subpart A.

IV. Proposed Action

EPA is proposing to approve the SIP revision submitted by Kentucky on December 22, 2021, addressing the base year emissions inventory requirements for the 2015 8-hour ozone NAAQS for the Cincinnati, OH-KY Area and Louisville, KY-IN Area. EPA proposes to find that the Commonwealth's submission meets the requirements of sections 110 and 182 of the CAA.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 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 they meet the criteria of the CAA. This proposed action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because

application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: July 19, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

[FR Doc. 2022–15776 Filed 7–25–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0397; FRL–10011–01–R4]

Air Plan Approval; South Carolina: New Source Review Updates

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of South Carolina, through the South Carolina Department of Health and Environmental Control (hereinafter referred to as SC DHEC or South Carolina) via a letter dated February 3, 2022. The SIP revisions include updates to South Carolina's Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) regulations. Specifically, the updates incorporate recent changes to the federal New Source Review (NSR) regulations, consisting of a clarification to the Project Emissions Accounting provisions, updates promulgated in the recent NSR Corrections Rule, and updates to reflect the regulation of greenhouse gases (GHGs) pursuant to the Tailoring Rule. EPA is proposing to approve these revisions pursuant to the Clean Air Act (CAA or Act) and implementing federal regulations.

DATES: Comments must be received on or before August 25, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2022–0397 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8966. Mr. Febres can also be reached via electronic mail at *febres-martinez.andres@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The PSD program is a preconstruction permitting program that requires ''major'' stationary sources of air pollution to obtain a PSD permit prior to beginning construction in areas classified as either in attainment with the National Ambient Air Quality Standards (NAAQS) or unclassifiable. *See* CAA section 165. EPA requires PSD SIPs to meet or exceed the minimum requirements codified at 40 CFR 51.166.[1]

The NNSR permitting program is a preconstruction permitting program that requires ''major'' stationary sources of air pollution to obtain an NNSR permit prior to beginning construction in areas classified as being in nonattainment with the NAAQS. *See* CAA section 173. EPA requires NNSR SIPs to meet the minimum requirements codified at 40 CFR 51.165.

Over the years, EPA has updated its rules implementing NNSR and PSD permitting at 40 CFR 51.165 and 40 CFR 51.166, respectively, and as a result of these amendments, states and localities similarly are required to update their SIP-approved rules to ensure consistency with the minimum requirements in federal PSD and NNSR rules. Collectively, EPA commonly refers to its PSD and NNSR permitting programs as major ''new source review'' permitting programs.

On February 3, 2022, SC DHEC submitted SIP revisions to EPA for approval that include changes to South Carolina's major NSR permitting regulations to make them more closely align with federal requirements for PSD and NNSR permitting based on recent updates to the federal NSR regulations.[2] Specifically, these changes update South Carolina's Regulation 61–62.5, Standard No. 7—*Prevention of Significant Deterioration* and Standard No. 7.1—*Nonattainment New Source Review.*[3]

EPA last approved updates to South Carolina's SIP-approved major NSR regulations on October 28, 2021 by acting on an April 24, 2020 submittal from South Carolina. *See* 86 FR 59646. Since the time of South Carolina's previous April 24, 2020 submittal to revise its major NSR rules, EPA has updated the federal major NSR regulations to clarify the Project Emissions Accounting provisions and to correct certain errors in the NSR

[1] Related rules setting forth the federal PSD program for areas without an approved PSD permitting program are codified at 40 CFR 52.21.

[2] EPA notes that the February 3, 2022, submittal was received by EPA on February 4, 2022. For clarity, EPA will refer to this submittal based on the date of the letter.

[3] EPA notes that under the February 3, 2022, cover letter, SC DHEC also submitted updates to the following State Regulations: 61–62.60, *South Carolina Designated Facility Plan and New Source Performance Standards;* Regulation 61–62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories;* and Regulation 61–62.70, *Title V Operating Permit Program.* However, South Carolina explains in the February 3, 2022, cover letter that these regulations are not part of the SIP, and they are not being requested for approval by EPA into the South Carolina SIP at this time.

regulations that have accumulated over time.[4] South Carolina's February 3, 2022, SIP submittal seeks to incorporate these updates to the federal rules into the EPA-approved major NSR regulations in the South Carolina SIP. Additionally, as discussed in detail below, South Carolina's SIP submittal seeks to incorporate into the South Carolina SIP updated PSD provisions related to the regulation of GHGs pursuant to the Tailoring Rule,[5] which was previously implemented in South Carolina through legislative action pursuant to South Carolina Joint Resolution H4888 (2010). EPA is proposing to approve these changes as meeting the requirements of the federal PSD and NNSR programs and as being consistent with the CAA. Additional details on South Carolina's February 3, 2022, revisions and EPA's analysis of the changes can be found below.

II. Analysis of the State's Submittal

As previously mentioned, the February 3, 2022, SIP submittal includes changes to South Carolina's PSD and NNSR regulations. Many of these changes are minor and are being proposed to align South Carolina's SIP-approved NSR rules with changes made by EPA in the federal PSD and NNSR regulations. More details on key updates included in the State's proposed changes to the South Carolina SIP are found in sections II.A and II.B below.

A. Regulation 61–62.5, Standard No. 7—Prevention of Significant Deterioration

The February 3, 2022, SIP submittal includes the following key changes to South Carolina's PSD regulations contained within Regulation 61–62.5, Standard No. 7 (hereinafter referred to as ''Standard No. 7'') in order to more closely align them with the federal PSD regulations: (1) Added a definition for the ''sum of the difference'' along with updated wording throughout Standard No. 7 to include this new definition, based on EPA's Project Emissions Accounting Rule; (2) added a definition for ''subject to regulation''; and (3) made several changes throughout the rule based on EPA's recent NSR Corrections Rule. More details on these changes to Standard No. 7 are included below. All other changes to Standard No. 7 are minor edits, such as adding brackets where needed, correcting grammatical errors, and renumbering sections based on added or deleted paragraphs throughout the rule.

i. Revisions To Reflect the Project Emissions Accounting Rule

Under paragraph (A)(2)(d)(vii), South Carolina adds a new definition for the ''sum of the difference,'' which is used for other definitions under paragraphs (A)(2)(d)(iii), (iv), and (vi). Subsequently, the definition for ''*hydrid test for projects that involve multiple types of emissions units,*'' under paragraph (A)(2)(d)(vi), was updated to include a reference to the new definition of the sum of the difference. These changes match those made to the federal PSD regulations at 40 CFR 51.166(a)(7)(iv)(*f*) and (*g*), through EPA's November 24, 2020, Project Emissions Accounting Rule.

ii. Added Definition of ''Subject to Regulation''

GHG emissions were covered for the first time by the PSD and title V operating permit programs effective on January 2, 2011 pursuant to the GHG Tailoring Rule. *See* 75 FR 31514 (June 3, 2010). In the June 3, 2010, notice, EPA described the implementation of the GHG Tailoring Rule, which consisted of the implementation of two steps (known as Step 1 and Step 2 of the GHG Tailoring Rule) and a commitment to establish a third step no later than July 1, 2012. Among the changes established in rulemaking for Step 1 and Step 2 of the GHG Tailoring tule, EPA added the definition for ''Subject to regulation'' to the federal PSD regulations at 40 CFR 51.166(b)(48).

In the implementation of Step 3, EPA decided against further phase-in of the GHG Tailoring Rule. Thus, the thresholds for determining PSD applicability based on emissions of GHGs remained the same as established in Steps 1 and 2 of the Tailoring Rule. *See* 77 FR 41051 (July 12, 2012). However, as part of Step 3 of the GHG Tailoring Rule, EPA revised the regulations under 40 CFR 52.21 to establish Plantwide Applicability Limits (PALs) for GHG emissions. *Id.* Prior to that, PALs were only available for GHGs on a mass basis. EPA's July 12, 2012, rule revised the PAL regulations in 40 CFR 52.21 to allow for GHG PALs to be established on a carbon dioxide equivalent (CO_2e)[6] basis, as well as a mass basis.

On June 23, 2014, the U.S. Supreme Court addressed GHG Tailoring Rule permitting requirements in *Utility Air Regulatory Group (UARG)* v. *EPA,* 573 U.S. 302 (2014). The Supreme Court upheld EPA's regulation of GHGs under the PSD program as applied to Step 1 sources (*i.e.,* sources that are ''major'' for purposes of PSD permitting based on non-GHG pollutants) but further held that EPA may not treat GHGs as air pollutants for the purpose of determining whether a source is a major source (or is undergoing a major modification). Thus, the Court invalidated the PSD and title V permitting requirements for GHG Step 2 sources. As a result of the Supreme Court decision, on April 10, 2015, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) vacated the regulations that implemented Step 2 of the GHG Tailoring Rule, including 40 CFR 51.166(b)(48)(v) and 40 CFR 52.21(b)(49)(v). *Coalition for Responsible Regulation, Inc.* v. *EPA,* 606 Fed. Appx. 6, 7 (D.C. Cir. 2015).

Subsequently, EPA promulgated a good cause final rule on August 19, 2015, entitled ''Prevention of Significant Deterioration and Title V Permitting for Greenhouse Gases: Removal of Certain Vacated Elements'' that removed from the federal regulations the portions of the PSD permitting provisions related to the GHG Step 2 sources that were vacated by the D.C. Circuit earlier that year. *See* 80 FR 50199.

In SC DHEC's February 3, 2022, SIP submittal, South Carolina adds a new definition for ''Subject to regulation'' under paragraph (B)(52) of Standard No. 7, which mostly matches the current federal PSD definition for ''[s]ubject to regulation'' found at 40 CFR 51.166(b)(48). The new definition in paragraph (B)(52) correctly excludes the vacated language mentioned above but adds language related to the implementation of GHG PALs in South Carolina's PSD program under subparagraph (B)(52)(a), which is not found under 51.166(b)(48). Although the language regarding GHG PALs is not found in the federal definition for ''subject to regulation'' under 40 CFR 51.166, the rulemaking for Step 3 of the GHG Tailoring Rule does add the GHG PAL language as part of the definition of ''subject to regulations'' under 40 CFR 52.21. *See* 77 FR 41051 at 41072. In that rulemaking, EPA notes that although the Agency is not adopting the GHG PAL

[4] The ''Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR): Project Emissions Accounting'' Rule was finalized on November 24, 2020. *See 85* FR 74890 (hereinafter ''Project Emissions Accounting Rule''). The ''New Source Review Regulations; Correction'' Rule was finalized on July 19, 2021. *See* 86 FR 37918 (hereinafter ''NSR Corrections Rule'').

[5] ''Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule'' (hereinafter referred to as the ''GHG Tailoring Rule''). *See* 75 FR 31514 (June 3, 2010).

[6] CO_2e emissions refers to emissions of six recognized GHGs which are scaled to equivalent CO_2 emissions by relative global warming potential values and are then summed together to determine a total equivalent emissions value. *See* 40 CFR 51.166 (b)(48)(ii) and 40 CFR 52.21(b)(49)(ii).

language into the existing PSD PAL provisions under 40 CFR 51.166, ''nothing in th[at] action is intended to restrict states from adopting th[ose], or similar, changes into their SIP-approved PAL program[s] if they choose to do so.'' *See id.* at 41070.

EPA additionally notes that although South Carolina appears to be adding provisions of the GHG Tailoring Rule to its PSD program for the first time, the State has been implementing these provisions through a joint resolution that became effective on July 1, 2010.[7] Adding the definition for ''subject to regulation'' into South Carolina's PSD rules merely streamlines the State's rules to current federal PSD standards in 40 CFR 51.166 and 52.21. However, this change has no practical effect because GHG provisions for PSD were already authorized on an interim basis by legislative action in South Carolina.

Finally, following the addition of this new definition, South Carolina renumbers the paragraphs that follow in order to accommodate the new entry. For the reasons described above, EPA believes that South Carolina's new definition is appropriate for incorporation into the SIP and is consistent with the federal PSD regulations.

iii. Revisions To Reflect Updates Contained in the NSR Corrections Rule

Additionally, based on EPA's July 19, 2021, NSR Corrections Rule, South Carolina makes several edits and deletions to Standard No. 7 to match the federal PSD regulations, and these are detailed below.

First, in paragraph (B)(8), which defines Best Available Control Technology (BACT), as well as in paragraph (J)(1), which includes provisions related to the Control Technology Review Provisions of 40 CFR 51.166(j), SC DHEC adds a reference to 40 CFR part 63 in accordance with updates contained in the NSR Corrections Rule.

Second, in paragraphs (B)(30)(c)(v)(1) and (B)(30)(c)(vi), SC DHEC removes references to 40 CFR 51.166 in accordance with the NSR Corrections Rule. These references are unnecessary because these paragraphs already referenced 40 CFR part 51, subpart I, which houses the federal PSD regulations contained within 40 CFR 51.166.

Third, under paragraphs (B)(32)(a)(i), (B)(32)(c)(viii), and (I)(1)(g)(viii), SC DHEC lowers the applicability threshold regarding consideration of fugitive emissions for municipal incinerators from the capacity to charge more than two-hundred and fifty (250) tons of refuse per day to the capacity to charge more than fifty (50) tons of refuse per day. This change broadens the applicability of the State's PSD rule for these types of sources and matches changes made to the federal PSD rule at 40 CFR 51.166(b)(1)(i)(*a*), (b)(1)(iii)(*h*), and (i)(1)(ii)(*h*) through the NSR Corrections Rule.

Fourth, SC DHEC deletes language within subparagraphs (I)(1)(a) through (e), (I)(1)(i), (I)(1)(j), (I)(6) through (11), (M)(1)(e), (M)(1)(g) and (M)(1)(h), from Standard No. 7 and inserts ''[Reserved]'' in their place. This deleted language matches the deletion of corresponding paragraphs in the federal PSD rules through the NSR Corrections Rule. Specifically, EPA removed paragraphs 40 CFR 52.21(i)(1)(i) through (v), (i)(1)(ix), (i)(1)(x), (i)(6) through (11), (m)(1)(v), (m)(1)(vii) and (m)(1)(viii).[8] In addition, South Carolina adds a new ''[Reserved]'' paragraph under (I)(12), which also matches the federal rules at 40 CFR 52.21(i)(12).[9]

Fifth, throughout several paragraphs in Standard No. 7, South Carolina updates internal references. Specifically, SC DHEC updates references in paragraphs (N)(1), (P)(6), (P)(7) and (P)(8) to align its rules with changes to the federal rules at 40 CFR 52.21(n)(1), (p)(6), (p)(7) and (p)(8), respectively.

iv. Other Minor Revisions

Additionally, SC DHEC makes a correction to one of the references in paragraph (AA)(12)(b), which incorrectly listed the requirements of the paragraph as being under ''(AA)(12)(c) through (AA)(12)(b)(i).'' The changes correct the reference to say ''(AA)(12)(c) through (AA)(12)(i)'' instead.

As previously mentioned, all the changes detailed above are either minor edits and corrections or updates to align South Carolina's rules with the minimum requirements for PSD plans (including updates responsive to EPA's Project Emissions Rule, the NSR Corrections Rule, and the Tailoring Rule). For these reasons, EPA is proposing to approve and incorporate into the South Carolina SIP the changes to Standard No. 7.

B. Regulation 61–62.5, Standard No. 7.1—Nonattainment New Source Review

The February 3, 2022, SIP submittal includes the following key changes to South Carolina's NNSR regulations contained within Regulation 61–62.5, Standard No. 7.1 (hereinafter referred to as ''Standard No. 7.1'') to more closely align with the federal NNSR regulations: (1) added a definition for the ''sum of the difference'' based on EPA's Project Emissions Accounting rule; (2) incorporated the federal interpollutant trading provisions for NNSR; and (3) made several changes throughout the rule based on EPA's NSR Corrections Rule. More details on these changes to Standard No. 7.1 are included below.

All other changes to South Carolina's Regulation 61–62.5, Standard No. 7.1, are minor edits, such as grammatical corrections, and renumbering sections based on added or deleted paragraphs throughout the rule.

i. Revisions To Reflect the Project Emissions Accounting Rule

Under paragraph (A)(9), SC DHEC adds a new definition for the ''sum of the difference,'' which is used within other definitions in paragraphs (A)(6), (7) and (8). Subsequently, the definition for ''*hydrid test for projects that involve multiple types of emissions units,*'' under paragraph (A)(8) was updated to include a reference to the new definition of the sum of the difference. These changes match those made to the federal NNSR regulations at 40 CFR 51.165(a)(2)(ii)(F) and (G), through EPA's Project Emissions Accounting Rule.

ii. Revisions To Reflect Updates Contained in the NSR Corrections Rule

Similar to the changes to South Carolina's PSD regulations explained in Section II.A., SC DHEC makes several edits and deletions to Standard No. 7.1 to align this rule with updates to 40 CFR 51.165 resulting from the NSR Corrections Rule. These changes are detailed further below.

[7] On June 11, 2010, the South Carolina Governor signed Joint Resolution H4888, which stated in relevant part that ''[i]n the event that the United States Environmental Protection Agency adopts rules that raise the threshold levels of GHG emissions that will trigger a requirement for emitters of greenhouse gases in South Carolina, notwithstanding any other provision of law, the rules shall be immediately effective in this State on an interim basis and implemented by the South Carolina Department of Health and Environmental Control pursuant to this joint resolution.'' *See https://www.scstatehouse.gov/sess118_2009-2010/bills/4888.htm* (last accessed on June 10, 2022). Subsequently, on March 4, 2011, SC DHEC submitted a letter to EPA confirming that the State has the authority to implement the Tailoring Rule thresholds in their PSD and title V programs. This letter to EPA can be found in the docket for this proposed action.

[8] Although these provisions are contained in 40 CFR 52.21 (which contains federal PSD plan rules rather than minimum requirements for state PSD plans), South Carolina previously adopted these provisions into its PSD plan.

[9] Although this provision is contained in 40 CFR 52.21 (which contains federal PSD plan rules rather than minimum requirements for state PSD plans), South Carolina previously adopted this provision into its PSD plan.

First, under paragraphs (A)(11)[10] and (B)(22), SC DHEC lowers the applicability threshold regarding consideration of fugitive emissions from for municipal incinerators from the capacity to charge more than two-hundred and fifty (250) tons of refuse per day to the capacity to charge more than fifty (50) tons of refuse per day. This change broadens the applicability of South Carolina's Standard No. 7.1 for these types of sources and matches changes made to the federal NNSR rules at 40 CFR 51.165(a)(1)(iv)(C)(*8*) and (a)(4)(viii) through the NSR Corrections Rule.

Although most of paragraphs (A)(11) and (B)(22) are appropriate for incorporation into the South Carolina SIP and match the current federal rules, the State-effective version includes a portion of the definition for ''Chemical process plants'' under (A)(11)(t) and (B)(22)(c)(xx) that has never been approved into the SIP. In particular, the language contained after ''Chemical process plant,'' which states that ''[t]he term chemical processing plants shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140,'' is not currently in the SIP.[11] Due to the ongoing review of the 2007 Ethanol Rule in regards to the federal NNSR regulations, SC DHEC notes in its February 3, 2022, cover letter that it is not requesting EPA to approve these portions of paragraphs (A)(11) and (B)(22) into the SIP at this time.[12]

Second, in paragraph (B)(5), South Carolina adds a reference to 40 CFR part 63 in accordance with updates contained in the NSR Corrections Rule. This paragraph already contains references to Parts 60 and 61 but based on changes to the federal NNSR rules at 40 CFR 51.165(a)(1)(xl), South Carolina adds the reference to Part 63 as well.

Third, in paragraphs (B)(21)(c)(v)(1) and (B)(21)(c)(vi), South Carolina removes the references to 40 CFR 51.166 in accordance with revisions arising from the NSR Corrections Rule. These references were incorrect to use in Standard No. 7.1 because 40 CFR 51.166 contains the Federal PSD regulations, rather than the federal NNSR regulations. Additionally, these references were unnecessary because these paragraphs already referenced 40 CFR part 51, subpart I, which house the federal NNSR regulations, found in 40 CFR 51.165.

Fourth, under paragraph (D)(6), which contains NNSR offset provisions, SC DHEC deletes an outdated reference to EPA's ''Recommended Policy on the Control of Volatile Organic Compounds (42 FR 35314, July 8, 1977).'' Instead, South Carolina points to 40 CFR 51.100(s), where a list of compounds with negligible photochemical reactivity can be found. According to the State's rule, emissions credit may be allowed only for hydrocarbons substituted with one of these compounds. This updated reference matches changes made to the federal NNSR rules at 51.165(a)(3)(ii)(D) through the NSR Corrections Rule.

Finally, under Section (H), specifically in paragraph (H)(1), South Carolina adopts corrections to the federal interprecursor offsetting rules, found at 40 CFR 51.165(a)(11), in order to delete vacated language regarding ozone interprecursor offsetting. Originally, the State-effective version of Section (H) contained language from the December 6, 2018, rule ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements'' (2018 Implementation Rule). *See* 83 FR 62998. These federal provisions were later vacated by the D.C. Circuit through a January 29, 2021, court decision. *See Sierra Club* v. *EPA,* 985 F.3d 1055 (D.C. Cir. 2021). Accordingly, on June 22, 2021, EPA removed this vacated language from 40 CFR 51.165(a)(11) through the NSR Corrections Rule.

South Carolina's previous proposed SIP revision addressing Standard No. 7.1, which was submitted to EPA on April 24, 2020, sought to incorporate Section (H), including the vacated language mentioned above, under paragraph (H)(1), into the SIP. Because of the court decision and vacatur, South Carolina later withdrew its request for EPA to incorporate Section (H) in its entirety into the SIP, through an April 20, 2021, withdrawal letter, and so this section is not currently found in the SIP-approved version of Standard No. 7.1. The February 3, 2022, SIP revision now submits a corrected version of Section (H), with the removal of the vacated language from paragraph (H)(1), for incorporation into the SIP. EPA has evaluated the revised provision and found that the language matches that of the federal NNSR regulation, found at 40 CFR 51.165(a)(11), and is proposing to incorporate it into the South Carolina SIP.

As previously mentioned, all the changes detailed above are either minor edits and corrections or are updates to align South Carolina's rules with minimum requirements in the federal NNSR rule found at 40 CFR 51.165, based on changes made through EPA's Project Emissions Rule and the NSR Corrections Rule. For these reasons, EPA is proposing to approve and incorporate into the South Carolina SIP the changes to Regulation 61–62.5, Standard No. 7.1, except for the parts of subparagraphs (A)(11)(t) and (B)(22)(c)(xx) noted above, as they relate to the Ethanol Rule Provisions of the federal NNSR regulations,

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, and as discussed in Sections I and II of this preamble, EPA is proposing to incorporate by reference South Carolina's Regulation 61–62.5, Standard No. 7—*Prevention of Significant Deterioration,* and Standard No. 7.1—*Nonattainment New Source Review,* both state effective on November 26, 2021, except for a portion of paragraphs (A)(11)(t) and (B)(22)(c)(xx) related to the Ethanol Rule Provisions, found in Regulation 61–62.5, Standard No. 7.1. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov*

[10] Paragraph (A)(10) is being renumbered to (A)(11).

[11] On May 1, 2007, EPA published in the **Federal Register** the 2007 Ethanol Rule (72 FR 24060), which amended EPA's PSD and NNSR regulations to exclude ethanol manufacturing facilities that produce ethanol by natural fermentation processes from the ''chemical process plants'' category under the regulatory definition of ''major stationary source.'' Shortly thereafter, EPA received a petition for reconsideration of the 2007 Ethanol Rule provisions from Natural Resources Defense Council (NRDC), which petition EPA initially denied on March 27, 2008. *See* 73 FR 24174 (March 27, 2008). In 2009, EPA received a second petition for reconsideration from NRDC, and NRDC also filed a petition for judicial review in the U.S. Court of Appeals for the District of Columbia Circuit challenging EPA's 2008 denial of its first petition for reconsideration. The court granted a joint motion to hold the case in abeyance, and the case has remained in abeyance. On October 21, 2019, EPA partially granted and partially denied the second petition for reconsideration. *See* 84 FR 59743 (November 6, 2019). Specifically, EPA granted the request for reconsideration with regard to the claim that the 2007 Ethanol Rule did not appropriately address the CAA section 193 anti-backsliding requirements for nonattainment areas. Concurrently, EPA denied the remainder of the requests for reconsideration. This means that states are now able to adopt the Ethanol Rule provisions for their PSD programs but are generally not choosing to do the same for their NNSR programs at this time.

[12] South Carolina's February 3, 2022, cover letter, additionally references a June 21, 2021, withdrawal letter, which was sent to EPA while the Agency was in the process of approving the State's last update to the NSR regulations into the SIP. In the February 3, 2020, letter, SC DHEC confirms that the intention of the June 21, 2021, withdrawal letter remains the same and that it is not requesting EPA to approve the Ethanol Rule provisions, found in Regulation 61–62.5, Standard No. 7.1, at this time.

and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Proposed Action

As described above, EPA is proposing to approve, with the exceptions noted above, the changes to the South Carolina Regulation 61–62.5, Standards No. 7—*Prevention of Significant Deterioration,* and Standard No. 7.1—*Nonattainment New Source Review,* both state effective on November 26, 2021. These changes were submitted by South Carolina on February 3, 2022.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

Because this proposed action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law, this proposed action for the State of South Carolina does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Therefore, this proposed action will not impose substantial direct costs on Tribal governments or preempt Tribal law. The Catawba Indian Nation (CIN) Reservation is located within the boundary of York County, South Carolina. Pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120 (Settlement Act), ''all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and are fully enforceable by all relevant state and local agencies and authorities.'' The CIN also retains authority to impose regulations applying higher environmental standards to the Reservation than those imposed by state law or local governing bodies, in accordance with the Settlement Act.

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, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: July 19, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

[FR Doc. 2022–15778 Filed 7–25–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 220720–0160]

RIN 0648–BK93

Pacific Halibut Fisheries; Catch Sharing Plan

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

ACTION: Proposed rule.

SUMMARY: Under the authority of the Northern Pacific Halibut Act of 1982, this action would create a permitting system for the Pacific halibut commercial and recreational charter halibut fisheries in International Pacific Halibut Commission (IPHC) Regulatory Area 2A off of Washington, Oregon, and California. In addition, this action would establish a regulatory framework for the Area 2A Pacific halibut directed commercial fishery that, consistent with the allocations and coastwide season dates set by the IPHC, allows NMFS to annually determine dates and times the fishery is open and set harvest limits for those periods of time. These permitting and management activities for Area 2A are currently performed by the IPHC; under this proposed rule, NMFS will implement these Area 2A-specific permitting and management activities.

DATES: Comments must be received on or before August 25, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0090, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2020–0090 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Scott Rumsey, c/o Kathryn Blair, West Coast Region, NMFS, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97232.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.),

confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted at the following website: *www.reginfo.gov/public/do/PRAMain.*

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, phone: 562–980–4034, fax: 562–980–4018, or email: *joshua.lindsay@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Northern Pacific Halibut Act of 1982 (Halibut Act), 16 U.S.C. 773–773k, gives the Secretary of Commerce (Secretary) general responsibility for implementing the provisions of the Convention between Canada and the United States for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Halibut Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (signed at Washington, DC, on March 29, 1979). The Halibut Act requires that the Secretary shall adopt regulations as may be necessary to carry out the purposes and objectives of the Halibut Convention and Halibut Act. 16 U.S.C. 773c. The Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration (NOAA), on behalf of the IPHC, publishes annual management measures governing the Pacific halibut fishery that have been recommended by the IPHC and accepted by the Secretary of State, with concurrence from the Secretary of Commerce. These management measures include coastwide and area-specific mortality limits (also known as allocations and subarea allocations), coastwide season dates, gear restrictions, Pacific halibut size limits for retention, and logbook requirements, among others. The IPHC apportions allocations for the Pacific halibut fishery among regulatory areas: Area 2A (Washington, Oregon, and California), Area 2B (British Columbia), Area 2C (Southeast Alaska), Area 3A (Central Gulf of Alaska), Area 3B (Western Gulf of Alaska), and Area 4 (subdivided into 5 areas, 4A through 4E, in the Bering Sea and Aleutian Islands of Western Alaska).

Additionally, as provided in the Halibut Act, the Regional Fishery Management Councils having authority for the geographic area concerned may develop, and the Secretary of Commerce may implement, regulations governing harvesting privileges among U.S. fishermen in U.S. waters that are in addition to, and not in conflict with, approved IPHC regulations (16 U.S.C. 773c(c)). The Pacific Fishery Management Council (Council) has exercised this authority by developing a catch sharing plan guiding the allocation of halibut, and management of recreational (or sport) fisheries for the IPHC's regulatory Area 2A. The Council's Catch Sharing Plan guides tribal, non-tribal commercial, and recreational halibut fishing off the U.S. west coast by prescribing an allocation formula for the allowable catch, and by describing the general season structure of the fisheries. Since 1988, the National Marine Fisheries Service (NMFS) has approved Catch Sharing Plans and implemented annual regulations consistent with the Catch Sharing Plans that allocate the IPHC regulatory Area 2A Pacific halibut allocation between tribal and non-tribal, and commercial and recreational harvesters. In 1995, NMFS approved a Council-recommended, long-term Catch Sharing Plan (60 FR 14651, March 20, 1995). The Council has recommended and NMFS has approved adjustments to the Catch Sharing Plan each year after discussion at the September and November Council meetings to address the changing needs of these fisheries. In addition, each year NMFS issues management measures to govern the recreational fishery (50 CFR 300.63(b)(1)). These measures include the recreational fishery seasons, allocations, closed areas, and bag limits for Area 2A.

Currently, the IPHC regulates and manages certain aspects of the commercial and recreational charter fisheries in Area 2A. As required under IPHC regulations, in order for a vessel to fish for Pacific halibut in Area 2A, either in the recreational charter fishery or the commercial fishery, the vessel must have a permit issued by the IPHC. (The term 'permit' is synonymous with 'license.' IPHC documents generally use 'license' and NMFS in this rule uses 'permit.') Specifically, the IPHC issues permits for Area 2A vessels participating in the recreational charter fishery and three non-tribal commercial fisheries: a directed commercial fishery, incidental catch of Pacific halibut in the West Coast sablefish fishery, and incidental catch of Pacific halibut in the West Coast salmon troll fishery. In addition, the IPHC sets management measures for the non-tribal directed commercial Pacific halibut fishery (directed commercial fishery), including fishing periods and associated fishing period limits which are announced via IPHC media releases. A fishing period is the period of time during the annual halibut season set by the IPHC when fishing for Pacific halibut is allowed and may span multiple days. A fishing period limit is the maximum amount of Pacific halibut that may be retained and landed by a vessel during one fishing period, and each vessel may only retain Pacific halibut up to the fishing period limit for its vessel class.

As part of this process, the IPHC sets an initial fishing period and fishing period limit in Area 2A for the directed commercial fishery and, if the IPHC determines that the directed commercial fishery allocation for Area 2A has not been exceeded or is not projected to be exceeded after the first fishing period, announces subsequent fishing periods and associated fishing period limits until the Area 2A allocation is or is projected to be reached. Over the last ten years, the number of fishing periods per year has varied between two and five fishing periods. The fishing season for the directed commercial fishery typically operates from late June through August, with fishing periods every other week until the Area 2A directed commercial fishery allocation has been or is projected to be reached. In the past six years (2016–2021), all but one year had three fishing periods; in 2020 there were five fishing periods. Between 2016 and 2021, the directed commercial allocation in Area 2A has ranged between 193,364 and 256,122 lb. (87.71 and 116.18 mt), and the IPHC set fishing periods and fishing period limits to remain within this allocation. As described previously, the Area 2A allocation is determined on an annual basis by the IPHC and may vary from year to year; therefore the directed commercial allocation, as derived through the Catch Sharing Plan's allocation framework, may vary on an annual basis. For most fishing periods during the 2016–2021 seasons, limits were generally set in ascending order, with smaller vessels receiving a lower limit and larger vessels receiving a higher limit. During the past six years, IPHC set one fishing period where all vessel classes were subject to the same fishing period limit. Prior to 2020, fishing periods were 10 hours, and, when setting limits, the IPHC considered the feasibility of a vessel achieving the fishing period limit within this duration of time. The fishing periods were extended to 58 hours

starting in 2020, after a recommendation from the Council to the IPHC and subsequent approval by NMFS, and the IPHC began to set limits under the assumption that more vessels would fish for and achieve the fishing period limit given the extended time for fishing.

Under this proposed action, NMFS would carry out some of the previously mentioned management activities currently conducted by the IPHC. Specifically, NMFS would assume responsibility for issuing vessels permits to fish for Pacific halibut in commercial and recreational charter fisheries in Area 2A, and for issuing annual management measures for the directed commercial fishery. These actions would be in addition to actions NMFS already undertakes such as issuing annual management measures for the Area 2A recreational fisheries (applicable to both charter and private anglers), consistent with the recommendations from the Council and the framework in the Council's Catch Sharing Plan.

Between 2017 and 2019, NMFS, the IPHC, and the Council discussed transitioning specific management activities of the Area 2A fishery from IPHC to NMFS as NMFS and the Council were seen as being able to better address the overlap of Pacific halibut management with domestic fisheries (*e.g.,* groundfish and salmon). At the June 2019 Council meeting, IPHC, NMFS, and the Council agreed to move forward with this transition, with a goal of completing the transition as expeditiously as possible, while maintaining the current management process and structure to minimize disruption in fishery operations. The Council heard public and industry perspectives on the transition of management of the Area 2A commercial halibut fisheries from IPHC to NMFS at its March, September, and November 2020 meetings. In developing this rule, NMFS took into account recommendations from the Council finalized at their November 2020 meeting.

The Council recommended NMFS adopt several permit management measures: issuing permits for all fisheries currently permitted by the IPHC, consisting of the directed, incidental sablefish and salmon commercial fisheries, and recreational charter vessels; setting permit application deadlines; and requiring proof of permit to be on the fishing vessel and made readily available upon request, regardless of the type of permit (*i.e.,* paper or electronic). NMFS considered these recommendations in proposing this rule.

During these Council discussions, the Council also noted that their intention was to continue to discuss directed commercial fishery management for upcoming fishing seasons during its September and November meetings, which are the same meetings during which the Council had previously developed recommendations for the IPHC on the directed commercial fishery, and during which it currently considers recommendations for the Area 2A recreational fishery and other recommendations to the IPHC.

Permitting for Commercial and Recreational Charter Vessels

Currently, no person shall fish for Pacific halibut from a vessel, nor possess Pacific halibut on board a vessel, used either for commercial fishing or as a charter vessel in Area 2A, unless the IPHC has issued a permit valid for fishing in Area 2A to that vessel. Under this proposed rule, NMFS would maintain this requirement for vessels to obtain a permit and would implement a NMFS permitting process. The IPHC issues permits for Area 2A fisheries through a website application and sets permit application deadlines to allow for processing and distribution of permits that aligns with start dates of the incidental and directed commercial fisheries. Under this action, NMFS proposes to use a web-based application with digital submission and delivery of the permit applications and proposes to allow participants to provide either digital or paper proof of permit upon request. Prior to 2020, only the official paper permit mailed by the IPHC to the applicant was allowed for enforcement purposes; after Council discussion with industry and enforcement representatives, the Council recommended that either digital or paper permits are acceptable, as there are no enforcement concerns with either format. NMFS is proposing applications for permits to fish for halibut in Area 2A be required to be submitted by the following dates: (1) incidental salmon fishery permit applications by March 1; (2) incidental sablefish fishery permit applications by March 1; (3) directed commercial fishery permit applications by February 15; and (4) recreational charter vessel applications 15 days prior to participation in the fishery.

NMFS notes that the permit application deadlines for the incidental salmon and sablefish fisheries are two weeks earlier than the same deadlines required by the IPHC (prior to 2020, the incidental sablefish permit deadline was March 15), and are one month before the fisheries open on April 1. The proposed deadline for the directed commercial fishery permit applications is over two months earlier than the existing IPHC deadline for this fishery. The earlier application deadlines will ensure adequate time for NMFS to issue permits in advance of the fishery season start dates and consider the number of applications when determining fishing period limits for the directed commercial fishery. NMFS will issue permits for all applications submitted with the required information and by the applicable deadline under this action. NMFS intends to require application information in addition to what the IPHC requires; specifically, those applying for directed commercial fishery permits must provide vessel length documentation from either the U.S. Coast Guard, state registration form, or a current marine survey. Fishery participants must obtain a new permit each year in order to participate in the Pacific halibut commercial and recreational charter fisheries in Area 2A.

The Regional Administrator may charge fees to cover administrative expenses related to processing and issuance of permits, processing change in ownership or change in vessel registration, divestiture, and appeals of permits. The amount of the fee would be determined in accordance with the NOAA Finance Handbook available at (*https://www.corporateservices.noaa.gov/finance/documents/NOAAFinanceHBTOC_09.06.19.pdf*) and specified on the application form. The fee may not exceed the administrative costs and must be submitted with the application for the application to be considered complete.

Directed Commercial Fishery

The non-tribal directed commercial Pacific halibut fishery is prosecuted in the area south of Point Chehalis, WA (46°53.30′ N lat.). As discussed previously, the IPHC currently manages the fishery through a series of fishing periods with fishing period limits based on the directed commercial fishery allocation distributed by vessel class. The IPHC permit application deadline for this fishery is currently April 30 and the first fishing period limits are announced by the IPHC in mid-to-late May, in advance of the first fishing period (which historically has occurred in late June). This fishery typically operates from late June through August, with fishing periods every other week until the Area 2A directed commercial fishery allocation has been or is projected to be reached. The IPHC uses fishing period limits based on vessel class and the number of permits issued

to help the fishery attain the Area 2A directed commercial fishery allocation while ensuring it is not exceeded. Under this proposed action, NMFS, instead of the IPHC, would implement annual management measures for the directed commercial fishery. Specifically, NMFS will implement directed commercial fishing period(s) and fishing period limits annually through annual proposed and final rules published in the **Federal Register** to ensure the directed commercial fishery allocation is not exceeded.

NMFS will consider any Council recommendations for the annual management measures, as well as public comments received on the proposed rule, when it implements fishing periods, fishing period limits, and any other directed commercial management measures. As noted previously, the Council has stated its intent to develop recommendations on annual directed fishery measures (*e.g.,* timing and duration of the fishing periods) through the same September and November meeting process currently utilized to provide recommendations to the IPHC at its annual meeting.

NMFS will determine directed commercial management measures, including fishing periods and fishing period limits, using similar decision criteria as the IPHC has used to set fishing periods and fishing period limits. The annual rulemaking process may include the announcement of more than one fishing period. In determining fishing period limits, NMFS will consider the directed commercial allocation, vessel class, the number of fishery permit applicants and projected number of participants per vessel class, the average catch of vessels compared to past fishing period limits, and other relevant factors. As the IPHC has done, in setting vessel limits NMFS will take into account the fact that smaller vessels are able to carry less gear and hold fewer Pacific halibut than larger vessels. The intent of these fishing period limits is to ensure that the Area 2A commercial directed fishery does not exceed the directed commercial allocation, while attempting to provide fair and equitable access across participants to an attainable amount of harvest.

As noted previously, NMFS is proposing a permit application deadline for the directed commercial fishery of February 15, which is over two months earlier than the date used by the IPHC. NMFS is proposing this earlier deadline to ensure that directed commercial fishery management measures are in place prior to the initial fishing period(s), traditionally opening in late June. The timing for the annual management measures rule with directed commercial management measures will allow for consideration of any Council recommendations that take place at the September and November meetings, public comments by stakeholders, and the Area 2A catch limit recommendation from the IPHC annual meeting. NMFS intends to annually publish a proposed rule after the Area 2A directed commercial allocation is determined by the IPHC (usually in late January or early February), and will publish a final rule as far in advance of the first directed commercial fishing period as practicable.

During the annual fishing season NMFS may establish additional fishing periods beyond those implemented at the start of the fishing year. For example, if, after the initial directed commercial fishing period(s), the fishery has not attained nor is projected to have attained the directed commercial allocation, NMFS will determine whether additional fishing period(s) are warranted. The decision to add fishing periods in addition to what was published as part of the annual rule establishing the season's management measures will be based on landings information from state fish tickets collected from the initial fishing period(s), and the dual objectives of providing additional opportunity to fishery participants while limiting the risk of exceeding the directed commercial allocation. As soon as practicable after the fishing periods announced in the annual management measures rule have occurred and after analyzing landings data, if the Regional Administrator determines that enough allocation remains to provide additional opportunity across all participants and vessel classes, additional fishing period(s) and applicable fishing period limits will be announced in the **Federal Register**. In the event NMFS takes this inseason action to add additional fishing period(s), fishing period limits will not vary across vessel class and instead will be set at the same amount for each vessel class. Generally, fewer vessels participate in each fishing period as the season progresses (the first fishing period has the highest level of participation and most pounds landed, followed by the second fishing period, etc.). For its inseason management, NMFS is proposing to set vessel limits equal across all size classes when additional fishing periods are determined to be warranted, because the number of vessels participating in each vessel class varies by fishing period and is not the same across years, and participants may choose to engage in any fishing period; thus there is a high degree of uncertainty in the number of participants per vessel class.

Classification

Regulations governing the U.S. fisheries for Pacific halibut are developed by the International Pacific Halibut Commission (IPHC), the Pacific Fishery Management Council, the North Pacific Fishery Management Council, and the Secretary of Commerce. Section 5 of the Northern Pacific Halibut Act of 1982 (Halibut Act, 16 U.S.C. 773c) allows the Regional Council having authority for a particular geographical area to develop regulations governing the allocation and catch of halibut in U.S. Convention waters as long as those regulations do not conflict with IPHC regulations.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, for the following reasons:

For Regulatory Flexibility Act (RFA) purposes only, NMFS has established a small business size standard for businesses, including their affiliates. A business primarily engaged in commercial fishing (North American Industry Classification System (NAICS) code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide (80 FR 81194, December 29, 2015). Previous analyses determined that charterboats are also small businesses (see 77 FR 5477 (February 3, 2012) and 76 FR 2876 (January 18, 2011)). Charter fishing operations are classified under NAICS code 487210, with a corresponding Small Business Association size standard of $7.5 million in annual receipts.

This action would create a permitting system for the Pacific halibut commercial and recreational charter halibut fisheries in Area 2A off of Washington, Oregon, and California. In addition, this action would establish a regulatory framework for the Area 2A Pacific halibut directed commercial fishery that, consistent with the coastwide season dates set by the IPHC, allows NMFS to annually determine

dates and times the fishery is open, fishing period limits, and a process to manage the fishery inseason. The proposed action was developed with input by industry, the public, and the IPHC, and was uncontroversial throughout the Council's public process.

In 2021, the IPHC issued 527 licenses to the recreational charter and commercial fleets for Area 2A. The IPHC issued 93 permits for recreational charter fishery, 190 permits for the directed commercial fishery, 44 permits for incidental commercial Pacific halibut caught in the sablefish, and 200 permits for incidental commercial Pacific halibut caught in the salmon troll fishery. Each affected vessel in these fisheries is a small business, and this proposed rule is considered to equally affect all of these small entities in the same manner, since all vessels participating in these Pacific halibut fisheries are required to have a permit. Additionally, since all vessels in the directed commercial fishery are small businesses, they would be equally affected by the regulatory framework and resulting management measures. Therefore, this rule would not create disproportionate costs between small and large vessels because there are no large entities involved in the halibut fisheries off of the West Coast.

The major impact of halibut management on small entities results from the annual IPHC catch limits for the fishery as a whole and for each IPHC regulatory area, determined independently from this proposed action. Profitability is more heavily influenced by the catch limit decision made by the IPHC, with sector and subarea allocations determined based on the Catch Sharing Plan framework and the allocation formula recommended by the Council. This proposed rule is unlikely to affect overall participation in the directed commercial fishery, since this action would maintain a permit requirement. This action is also unlikely to change the profitability in the commercial and recreational charter fisheries, since profitability is dependent on the amount of allocation available and market forces independent of this action. Therefore, this action will equally impact all vessels in both commercial and recreational charter fisheries, and these revisions will not significantly reduce profit for a substantial number of small entities.

For these reasons, NMFS concludes that the proposed action, if adopted, will not have a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required, and none has been prepared.

This proposed rule contains a collection-of-information requirement subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). This rule proposes to revise the existing requirements for the collection of information titled ''Northwest Region Federal Fisheries Permits'' (OMB Control Number 0648–0203) by adding a Pacific halibut permit for recreational charter fisheries and a Pacific halibut permit for the commercial fishery. This change will increase the number of respondents for this collection by 550 respondents annually. It will also increase the cost of the collection by $29,150. Public reporting burden for the Pacific halibut permits is estimated to average 20 minutes per respondent, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; 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, including through the use of automated collection techniques or other forms of information technology. Submit comments on these or any other aspects of the collection of information at *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review'' or by using the search function and entering the control number or title of the collection.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Antarctica, Canada, Exports, Fish, Fisheries, Fishing, Imports, Indians, Labeling, Marine resources, Reporting and recordkeeping requirements, Russian Federation, Transportation, Treaties, Wildlife.

Dated: July 20, 2022.

Kimberly Damon-Randall,

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

For the reasons set out in the preamble, 50 CFR part 300, subpart E, is proposed to be amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart E—Pacific Halibut Fisheries

■ 1. The authority citation for part 300, subpart E, continues to read as follows:

Authority: 16 U.S.C. 773–773k.

■ 2. In § 300.61, add definitions for ''Fishing period,'' ''Fishing period limit,'' ''Permit,'' ''Vessel class'' in alphabetical order to read as follows:

§ 300.61 Definitions.

* * * * *

Fishing period means, for purposes of commercial fishing in Commission regulatory Area 2A, dates and/or hours when fishing for Pacific halibut in Area 2A is allowed.

Fishing period limit means, for purposes of commercial fishing in Commission regulatory Area 2A, the maximum amount of Pacific halibut that may be retained and landed by a vessel during one fishing period in Area 2A.

* * * * *

Permit means, for purposes of commercial fishing in Commission regulatory Area 2A, a Pacific halibut fishing permit for Area 2A issued by NMFS pursuant to § 300.63(f).

* * * * *

Vessel class means, for purposes of commercial fishing in Commission regulatory Area 2A, a group of vessels within a specific range of overall length (in feet) (46 CFR 69.9), as designated by the letter A–H pursuant to § 300.63(g).

■ 3. In § 300.63, add paragraphs (f) and (g) to read as follows:

§ 300.63 Catch sharing plan and domestic management measures in Area 2A.

* * * * *

(f) *Pacific Halibut Permits for IPHC Regulatory Area 2A*—(1) *General.* (i) This section applies to persons and vessels that fish for Pacific halibut, or land and retain Pacific halibut, in IPHC Regulatory Area 2A. No person shall fish for Pacific halibut from a vessel, nor land or retain Pacific halibut on board a vessel, used either for commercial fishing or as a recreational charter vessel in IPHC Regulatory Area 2A, unless the NMFS West Coast Region has issued a permit valid for fishing in IPHC Regulatory Area 2A for that vessel.

(ii) A permit issued for a vessel operating in the Pacific halibut fishery in IPHC Regulatory Area 2A shall be valid for one of the following, per paragraph (d) of this section:

(A) The incidental catch during the salmon troll fishery specified in paragraph (b)(2) of this section;

(B) The incidental catch during the sablefish fishery specified in paragraph (b)(3) of this section;

(C) The non-tribal directed commercial fishery during the fishing periods specified in paragraph (g)(1) of this section;

(D) Both the incidental catch during the sablefish fishery specified in paragraph (b)(3) of this section and the non-tribal directed commercial fishery during the fishing periods specified in paragraph (g)(1) of this section; or

(E) The recreational charter fishery.

(iii) A permit issued under paragraph (f) of this section is valid only for the vessel for which it is registered. A change in ownership, documentation, or name of the registered vessel, or transfer of the ownership of the registered vessel will render the permit invalid.

(iv) A vessel owner must contact NMFS if the vessel for which the permit is issued is sold, ownership of the vessel is transferred, the vessel is renamed, or any other reason for which the documentation of the vessel is changed as the change would invalidate the current permit. A new permit application is required if there is a change in any documentation of the vessel. To submit a new permit application follow the procedures outlined under paragraph (f)(2) of this section. If the documentation of the vessel is changed after the deadline to apply for a permit has passed as described at paragraph (f)(2)(ii) of this section, the vessel owner may contact NMFS and provide information on the reason for the documentation change and all permit application information described at paragraph (f)(2) of this section. NMFS may issue a permit, or decline to issue a permit and the applicant may appeal per paragraph (f)(3) of this section.

(v) A permit issued under paragraph (f) of this section must be carried on board that vessel at all times and the vessel operator shall allow its inspection by any authorized officer. The format of this permit may be electronic or paper.

(vi) No individual may alter, erase, mutilate, or forge any permit or document issued under this section. Any such permit or document that is intentionally altered, erased, mutilated, or forged is invalid.

(vii) Permits issued under paragraph (f) of this section are valid only during the calendar year (January 1–December 31) for which it was issued.

(viii) NMFS may suspend, revoke, or modify any permit issued under this section under policies and procedures in title 15 of the U.S. Code, 15 CFR part 904, or other applicable regulations in this chapter.

(2) *Applications*—(i) *Application form.* To obtain a permit, an individual must submit a complete permit application to the NMFS West Coast Region Sustainable Fisheries Division (NMFS) through the NOAA Fisheries Pacific halibut web page at [*web address will be provided when the final rule is published*]. A complete application consists of:

(A) An application form that contains valid responses for all data fields, including information and signatures.

(B) A current copy of the U.S. Coast Guard Documentation Form or state registration form or current marine survey.

(C) Payment of required fees as discussed in paragraph (f)(2)(iv) of this section.

(D) Additional documentation NMFS may require as it deems necessary to make a determination on the application.

(ii) *Deadlines.* (A) Applications for permits for the directed commercial fishery in Area 2A must be received by NMFS no later than 2359 PST on February 15, or by 2359 PST the next business day in February if February 15 is a Saturday, Sunday, or Federal holiday.

(B) Applications for permits which allow for incidental catch of Pacific halibut during the salmon troll fishery and the sablefish primary fishery in Area 2A must be received by NMFS no later than 2359 PST March 1, or by 2359 PST the next business day in March if March 1 is a Saturday, Sunday, or Federal holiday.

(C) Applications for permits for recreational charter vessels which allow for catch of Pacific halibut during the recreational fishery must be received a minimum of 15 days before intending to participate in the fishery, to allow for processing the permit application.

(iii) *Application review and approval.* NMFS shall issue a vessel permit upon receipt of a completed permit application submitted on the NOAA Fisheries website no later than the day before the start date of the fishery the applicant selected. If the application is not approved, NMFS will issue an initial administrative decision (IAD) that will explain the denial in writing. The applicant may appeal NMFS' determination following the process at paragraph (f)(3) of this section. NMFS will decline to act on a permit application that is incomplete or if the vessel or vessel owner is subject to sanction provisions of the Magnuson-Stevens Act at 16 U.S.C. 1858(a) and implementing regulations at 15 CFR part 904, subpart D.

(iv) *Permit fees.* The Regional Administrator may charge fees to cover administrative expenses related to processing and issuance of permits, processing change in ownership or change in vessel registration, divestiture, and appeals of permits. The amount of the fee is determined in accordance with the procedures of the NOAA Finance Handbook for determining administrative costs. Full payment of the fee is required at the time a permit application is submitted.

(3) *Appeals.* In cases where the applicant disagrees with NMFS's decision on a permit application, the applicant may appeal that decision to the Regional Administrator. This paragraph (f)(3) describes the procedures for appealing the IAD on permit actions made in this title under this subpart.

(i) *Who may appeal?* Only an individual who received an IAD that disapproved any part of their application may file a written appeal. For purposes of this section, such individual will be referred to as the ''permit applicant.''

(ii) *Appeal process.* (A) The appeal must be in writing, must allege credible facts or circumstances to show why the criteria in this subpart have been met, and must include any relevant information or documentation to support the appeal. The permit applicant may request an informal hearing on the appeal.

(B) Appeals must be mailed or faxed to: National Marine Fisheries Service, Northwest Region, Sustainable Fisheries Division, ATTN: Appeals, 7600 Sand Point Way NE, Seattle, WA 98115; Fax: 206–526–6426; or delivered to National Marine Fisheries Service at the same address.

(C) Upon receipt of an appeal authorized by this section, the Regional Administrator will notify the permit applicant, and may request additional information to allow action on the appeal.

(D) Upon receipt of sufficient information, the Regional Administrator will decide the appeal in accordance with the permit provisions set forth in this section at the time of the application, based upon information relative to the application on file at NMFS and any additional information

submitted to or obtained by the Regional Administrator, the summary record kept of any hearing and the hearing officer's recommended decision, if any, and such other considerations as the Regional Administrator deems appropriate. The Regional Administrator will notify all interested persons of the decision, and the reasons for the decision, in writing, normally within 30 days of the receipt of sufficient information, unless additional time is needed for a hearing.

(E) If a hearing is requested, or if the Regional Administrator determines that one is appropriate, the Regional Administrator may grant an informal hearing before a hearing officer designated for that purpose after first giving notice of the time, place, and subject matter of the hearing to the applicant. The appellant, and, at the discretion of the hearing officer, other interested persons, may appear personally or be represented by counsel at the hearing and submit information and present arguments as determined appropriate by the hearing officer. Within 30 days of the last day of the hearing, the hearing officer shall recommend in writing a decision to the Regional Administrator.

(F) The Regional Administrator may adopt the hearing officer's recommended decision, in whole or in part, or may reject or modify it. In any event, the Regional Administrator will notify interested persons of the decision, and the reason(s) therefore, in writing, within 30 days of receipt of the hearing officer's recommended decision. The Regional Administrator's decision will constitute the final administrative action by NMFS on the matter.

(iii) *Timing of appeals.* (A) For permit issued under paragraph (f) of this section, if an applicant appeals an IAD, the appeal must be postmarked, faxed, or hand delivered to NMFS no later than 60 calendar days after the date on the IAD. If the applicant does not appeal the IAD within 60 calendar days, the IAD becomes the final decision of the Regional Administrator acting on behalf of the Secretary of Commerce.

(B) Any time limit prescribed in this section may be extended for a period not to exceed 30 days by the Regional Administrator for good cause, either upon his or her own motion or upon written request from the appellant stating the reason(s) therefore.

(iv) *Address of record.* For purposes of the appeals process, NMFS will establish as the address of record, the address used by the permit applicant in initial correspondence to NMFS. Notifications of all actions affecting the applicant after establishing an address of record will be mailed to that address, unless the applicant provides NMFS, in writing, with any changes to that address. NMFS bears no responsibility if a notification is sent to the address of record and is not received because the applicant's actual address has changed without notification to NMFS.

(v) *Status of permits pending appeal.* (A) For all permit actions, the permit registration remains as it was prior to the request until the final decision has been made.

(B) [Reserved]

(g) *Non-tribal directed commercial fishery management.* Each year a portion of Area 2A's overall fishery limit is allocated consistent with the Pacific Fishery Management Council's Catch Sharing Plan to the non-tribal directed commercial fishery and published pursuant to § 300.62. The non-tribal directed commercial fishery takes place in the area south of Point Chehalis, WA (46°53.30′ N lat.).

(1) *Management measures.* Annually, NMFS will determine and publish in the **Federal Register** annual management measures for the upcoming fishing year for the non-tribal directed commercial fishery. This will include dates and lengths for the fishing periods for the Area 2A non-tribal directed commercial fishery, as well as the associated fishing period limits.

(i) *Fishing periods.* NMFS will determine the fishing periods, *e.g.* dates and/or hours that permittees may legally harvest halibut in Area 2A, on an annual basis. This determination will take into account any recommendations provided by the Pacific Fishery Management Council and comments received by the public during the public comment period on the proposed annual management measures rule. The intent of these fishing periods is to ensure the Area 2A Pacific halibut directed commercial allocation is achieved but not exceeded.

(ii) *Fishing period limits.* NMFS will establish fishing period limits, *e.g.* the maximum amount of Pacific halibut that a vessel may retain and land during a specific fishing period, and assign those limits according to vessel class for each fishing period. Fishing period limits may be different across vessel classes (except as described in paragraph (g)(1)(iii) of this section). NMFS will determine fishing period limits following the considerations listed in paragraph (g)(1)(ii)(A) of this section. The intent of these fishing period limits is to ensure that the Area 2A commercial directed fishery does not exceed the directed commercial allocation, while attempting to provide fair and equitable access across fishery participants to an attainable amount of harvest. The limits will be published in annual management measures rules in the **Federal Register** along with a description of the considerations used to determine them.

(A) *Considerations.* When determining fishing period(s) and associated fishing period limits for the directed commercial fishery, NMFS will consider the following factors:

(*1*) The directed commercial fishery allocation;

(*2*) Vessel class;

(*3*) Number of fishery permit applicants and projected number of participants per vessel class;

(*4*) The average catch of vessels compared to past fishing period limits; and

(*5*) Other relevant factors.

(B) *Vessel classes.* Vessel classes are based on overall length (defined at 46 CFR 69.9) shown in the following table:

TABLE 1 TO PARAGRAPH (g)(1)(ii)(B)

Overall length (in feet)	Vessel class
1–25	A
26–30	B
31–35	C
36–40	D
41–45	E
46–50	F
51–55	G
56+	H

(iii) *Inseason action to add fishing periods and associated fishing period limits.* Fishing periods in addition to those originally implemented at the start of the fishing year may be warranted in order to provide the fishery with opportunity to achieve the Area 2A directed commercial fishery allocation, if performance of the fishery during the initial fishing period(s) is different than expected and the directed commercial allocation is not attained through the initial period(s). If NMFS makes the determination that sufficient allocation remains to warrant additional fishing period(s) without exceeding the allocation for the Area 2A directed commercial fishery, the additional fishing period(s) and fishing period limits may be added during the fishing year. If NMFS determines fishing period(s) in addition to those included in an annual management measures rule is warranted, NMFS will set the fishing period limits equal across all vessel classes. The fishing period(s) and associated fishing period limit(s) will be announced in the **Federal Register** and concurrent publication on the hotline. If the amount of directed commercial allocation remaining is determined to be insufficient for an additional fishing

period, the allocation is considered to be taken and the fishery will be closed, as described at paragraph (g)(2) of this section.

(2) *Automatic closure of the non-tribal directed commercial fishery.* The NMFS Regional Administrator or designee will initiate automatic management actions without prior public notice or opportunity to comment. These actions are nondiscretionary and the impacts must have been previously been taken into account.

(i) If NMFS determines that the non-tribal directed commercial fishery has attained its annual allocation or is projected to attain its allocation if additional fishing was to be allowed, the Regional Administrator will take automatic action to close the fishery, via announcement in the **Federal Register** and concurrent notification on the telephone hotline at 206–526–6667 or 800–662–9825.

(ii) [Reserved]

[FR Doc. 2022–15889 Filed 7–25–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 87, No. 142

Tuesday, July 26, 2022

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

Food and Nutrition Service

Child and Adult Care Food Program: National Average Payment Rates, Day Care Home Food Service Payment Rates, and Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes for the Period July 1, 2022 Through June 30, 2023

AGENCY: Food and Nutrition Service, Agriculture (USDA).

ACTION: Notice.

SUMMARY: This notice announces the annual adjustments to the national average payment rates for meals and snacks served in child care centers, outside-school-hours care centers, at-risk afterschool care centers, and adult day care centers; the food service payment rates for meals and snacks served in day care homes; and the administrative reimbursement rates for sponsoring organizations of day care homes, to reflect changes in the Consumer Price Index. Further adjustments are made to these rates to reflect the higher costs of providing meals in Alaska and Hawaii. The adjustments contained in this notice are made on an annual basis each July, as required by the laws and regulations governing the Child and Adult Care Food Program.

Overall, reimbursement rates this year for the Child and Adult Care Food Program increased compared to last year.

DATES: These rates are effective from July 1, 2022 through June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Penny Burke, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, United States Department of Agriculture, 1320 Braddock Place, Suite 401, Alexandria, Virginia 22314, 303–844–0357.

SUPPLEMENTARY INFORMATION:

Temporary Adjustments Authorized Under the Keep Kids Feed Act of 2022

Child and Adult Care Food Program institutions face continued challenges related to the COVID–19 pandemic. To help alleviate some of those challenges, Section 3 of the Keep Kids Fed Act of 2022 (Public Law 117–158) provides temporary additional funding for each meal and supplement served. This additional reimbursement amount will be available beginning July 1, 2022 and ending on June 30, 2023. The law temporarily provides an additional reimbursement in the amount of 10 cents for each meal and supplement served under the program authorized by section 17 of the Richard B. Russell National School Act (42 U.S. C. 1766). Additionally, the Keep Kids Fed Act of 2022 (Public Law 117–158) authorized a tier II family or group day care home described in subsection (f)(3)(A)(iii) of section 17 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766) to be considered a tier I family or group day care home for purposes of the program authorized under that section for the same period. This temporary measure will provide tier II homes with tier I reimbursement rates only for the time period beginning July 1, 2022 and ending on June 30, 2023.

Background

Pursuant to sections 4, 11, and 17 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753, 1759a and 1766), section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) and 7 CFR 226.4, 226.12 and 226.13 of the Program regulations, notice is hereby given of the new payment rates for institutions participating in the Child and Adult Care Food Program (CACFP). As provided for under the law, all rates in the CACFP must be revised annually, on July 1, to reflect changes in the Consumer Price Index (CPI), published by the Bureau of Labor Statistics of the United States Department of Labor, for the most recent 12-month period. These rates are in effect during the period July 1, 2022 through June 30, 2023.

Adjusted Payments

The following national average payment factors and food service payment rates for meals and snacks are in effect from July 1, 2022 through June 30, 2023. All amounts are expressed in dollars or fractions thereof. Due to a higher cost of living, the reimbursements for Alaska and Hawaii are higher than those for all other States. The District of Columbia, Virgin Islands, Puerto Rico, and Guam use the figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods, which institutions receive as additional assistance for each lunch or supper served to participants under the Program. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**. Adjustments to the national average payment rates for all meals served under the Child and Adult Care Food Program are rounded down to the nearest whole cent.

National Average Payment Rates for Centers (Including Temporary Increases Authorized by the Keep Kid Fed Act Which Expire on June 30, 2023)

The changes in the national average payment rates for centers reflect a 7.40 percent increase during the 12-month period from May 2021 to May 2022 (from 303.481 in May 2021, as previously published in the **Federal Register**, to 325.952 in May 2022) in the food away from home series of the CPI for All Urban Consumers.

Payments for breakfasts served are: *Contiguous States*—paid rate—45 cents (12 cent increase from 2021–2022 annual level), reduced price rate—1 dollar and 91 cents (24 cents increase), free rate—2 dollar and 21 cents (24 cents increase); *Alaska*—paid rate—64 cents (14 cent increase), reduced price rate—3 dollars and 18 cents (33 cents increase), free rate—3 dollars and 48 cents (33 cents increase); *Hawaii*—paid rate –50 cents (12 cent increase), reduced price rate—2 dollars and 26 cents (27 cents increase), free rate—2 dollars and 56 cents (27 cents increase).

Payments for lunch or supper served are: *Contiguous States*—paid rate—47 cents (12 cents increase from 2021–2022 annual level), reduced price rate—3 dollars and 63 cents (37 cents increase), free rate—4 dollars and 03 cents (37 cents increase); *Alaska*—paid rate—71 cents (14 cents increase), reduced price rate—6 dollars and 07 cents (53 cents increase), free rate—6 dollars and 47 cents (53 cents increase); *Hawaii*—paid rate—54 cents (13 cents increase), reduced price rate—4 dollars and 30

cents (42 cents increase), free rate—4 dollars and 70 cents (42 cents increase).

Payments for snack served are: *Contiguous States*—paid rate—19 cents (10 cents increase from 2021–2022 annual level), reduced price rate—64 cents (14 cents increase), free rate—1 dollar and 18 cents (18 cents increase); *Alaska*—paid rate—26 cents (12 cents increase), reduced price rate—97 cents (16 cents increase), free rate—1 dollar and 85 cents (22 cents increase); *Hawaii*—paid rate—21 cents (11 cent increase), reduced price rate—73 cents (15 cents increase), free rate—1 dollar and 36 cents (19 cents increase).

Food Service Payment Rates for Day Care Homes (Including Temporary Increases Authorized by the Keep Kids Fed Act of 2022 Which Expires on June 30, 2023)

The changes in the food service payment rates for day care homes reflect a 11.91 percent increase during the 12-month period from May 2021 to May 2022 (from 255.516 in May 2021, as previously published in the **Federal Register**, to 285.953 in May 2022) in the food at home series of the CPI for All Urban Consumers.

Payments [1] for breakfast served are: *Contiguous States*—Tier I—1 dollar and 66 cents (26 cents increase from 2021–2022 annual level) and Tier II—1 dollar and 66 cents (1 dollar and 15 cent increase); *Alaska*—Tier I—2 dollars and 59 cents (36 cent increase) and Tier II—2 dollars and 59 cents (1 dollar and 80 cent increase); *Hawaii*—Tier I—1 dollar and 91 cents (28 cent increase) and Tier II—1 dollar and 91 cents (1 dollar 33 cent increase).

Payments for lunch and supper served are: *Contiguous States*—Tier I—3 dollars and 04 cents (41 cents increase from 2021–2022 annual level) and Tier II—3 dollars and 04 cents (1 dollar and 45 cent increase); *Alaska*—Tier I—4 dollars and 87 cents (61 cents increase) and Tier II—4 dollars and 87 cents (2 dollar and 30 cent increase); *Hawaii*—Tier I—3 dollars and 55 cents (47 cents increase) and Tier II—3 dollars and 55 cents (1 dollar 69 cent increase).

Payments for snack served are: *Contiguous States*—Tier I—97 cents (19 cents increase from 2021—2022 annual level) and Tier II—97 cents (76 cents increase); *Alaska*—Tier I—1 dollar and 52 cents (25 cent increase) and Tier II—Tier I—1 dollar and 52 cents (1 dollar 17 cent increase); *Hawaii*—Tier I—1 dollar and 12 cents (21 cents increase) and Tier II—1 dollar and 12 cents (87 cents increase).

Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes

The changes in the administrative reimbursement rates for sponsoring organizations of day care homes reflect an 8.58 percent increase during the 12-month period, May 2021 to May 2022 (from 269.195 in May 2021, as previously published in the **Federal Register**, to 292.296 in May 2022) in the series for all items of the CPI for All Urban Consumers.

Monthly administrative payments to sponsors for each sponsored day care home are: *Contiguous States*—Initial 50 homes—137 dollars (11 dollars increase from 2021—2022 annual level), next 150 homes—104 dollars (8 dollars increase), next 800 homes—81 dollars (6 dollars increase), each additional home—72 dollars (6 dollars increase); *Alaska*—Initial 50 homes—221 dollars (17 dollars increase), next 150 homes—169 dollars (14 dollars increase), next 800 homes—132 dollars (11 dollars increase), each additional home—116 dollars (9 dollars increase); *Hawaii*—Initial 50 homes—160 dollars (13 dollars increase), next 150 homes—122 dollars (10 dollars increase), next 800 homes—95 dollars (7 dollars increase), each additional home—84 dollars (7 dollars increase).

Payment Chart Including Additional Temporary Reimbursement From the Keep Kids Fed Act of 2022

The following chart illustrates the national average payment factors and food service payment rates for meals and snacks in effect for the school year beginning July 1, 2022 and ending June 30, 2022 and includes the additional reimbursement authorized by the Keep Kids Fed Act of 2022 (Pub. L. 117–158).

BILLING CODE 3410–30–P

[1] The Keep Kids Fed Act of 2022 (Pub. L. 117–158) authorized an additional 10 cent reimbursement per meal or supplement served under the program for the school year beginning July 1, 2022 and ending June 30, 2023. Additionally, all Tier II family daycare homes shall be reimbursed at the Tier I rate for the school year beginning July 1, 2022 and ending June 30, 2023.

Table 1: Temporary Reimbursement Payment Chart
CHILD AND ADULT CARE FOOD PROGRAM (CACFP)
Per Meal Rates in Whole or Fractions of U.S. Dollars

Effective July 1, 2022 through June 30, 2023

Temporary Additional Reimbursement included from Keep Kids Feed Act 2022

CENTERS[2]		BREAKFAST	LUNCH AND SUPPER[1]	SUPPLEMENT
CONTIGUOUS STATES	PAID	0.45	0.47	0.19
	REDUCED PRICE	1.91	3.63	0.64
	FREE	2.21	4.03	1.18
ALASKA	PAID	0.64	0.71	0.26
	REDUCED PRICE	3.18	6.07	0.97
	FREE	3.48	6.47	1.85
HAWAII	PAID	0.50	0.54	0.21
	REDUCED PRICE	2.26	4.30	0.73
	FREE	2.56	4.70	1.36

DAY CARE HOMES[2]	BREAKFAST		LUNCH AND SUPPER		SUPPLEMENT	
	TIER I	TIER II	TIER I	TIER II	TIER I	TIER II
CONTIGUOUS STATES	1.66	1.66	3.04	3.04	0.97	0.97
ALASKA	2.59	2.59	4.87	4.87	1.52	1.52
HAWAII	1.91	1.91	3.55	3.55	1.12	1.12

ADMINISTRATIVE REIMBURSEMENT RATES FOR SPONSORING ORGANIZATIONS OF DAY CARE HOMES *Per Home/Per Month Rates in U.S. Dollars*	**Initial 50**	**Next 150**	**Next 800**	**Each Additional**
CONTIGUOUS STATES	137	104	81	72
ALASKA	221	169	132	116
HAWAII	160	122	95	84

[1]These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each CACFP lunch or supper served to participants. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the Federal Register.
[2]The Keep Kids Fed Act of 2022 (P.L. 117-158) provides an additional 10 cents for each meal and supplement served and allows tier II day care homes to be reimbursed at the tier I rate for the time period starting July 1, 2022 ending on June 30,2023.

Base Payment Chart (Excludes the Temporary Increases Authorized by Keep Kids Fed Act of 2022)

The following chart shows the national average payment factors and food service payment rates for meals and snacks in effect from July 1, 2022 through June 30, 2023. These rates reflect the annual adjustments as required by the laws and regulations governing the Child and Adult Care Food Program and do not include the temporary increases authorized by Keep Kids Fed Act of 2022 (Pub. L. 117–158).

Table 2: Base Payment Chart[2]

CHILD AND ADULT CARE FOOD PROGRAM (CACFP)

Per Meal Rates in Whole or Fractions of U.S. Dollars

Effective from July 1, 2022 - June 30, 2023

CENTERS		BREAKFAST	LUNCH AND SUPPER[1]	SUPPLEMENT
CONTIGUOUS STATES	PAID	0.35	0.37	0.09
	REDUCED PRICE	1.81	3.53	0.54
	FREE	2.11	3.93	1.08
ALASKA	PAID	0.54	0.61	0.16
	REDUCED PRICE	3.08	5.97	0.87
	FREE	3.38	6.37	1.75
HAWAII	PAID	0.40	0.44	0.11
	REDUCED PRICE	2.16	4.20	0.63
	FREE	2.46	4.60	1.26

DAY CARE HOMES	BREAKFAST		LUNCH AND SUPPER		SUPPLEMENT	
	TIER I	TIER II	TIER I	TIER II	TIER I	TIER II
CONTIGUOUS STATES	1.56	0.56	2.94	1.78	0.87	0.24
ALASKA	2.49	0.87	4.77	2.88	1.42	0.39
HAWAII	1.81	0.65	3.45	2.08	1.02	0.28

ADMINISTRATIVE REIMBURSEMENT RATES FOR SPONSORING ORGANIZATIONS OF DAY CARE HOMES *Per Home/Per Month Rates in U.S. Dollars*	Initial 50	Next 150	Next 800	Each Additional
CONTIGUOUS STATES	137	104	81	72
ALASKA	221	169	132	116
HAWAII	160	122	95	84

[1]These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each CACFP lunch or supper served to participants. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the *Federal Register*.

[2]This chart **does not** contain the KKFA rate increases

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. This notice has been determined to be exempt under Executive Order 12866.

CACFP is listed in the Catalog of Federal Domestic Assistance under No. 10.558 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR 415.3–415.6).

This notice imposes no new reporting or recordkeeping provisions that are subject to OMB review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3518).

Authority: Sections 4(b)(2), 11a, 17(c) and 17(f)(3)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753(b)(2), 1759a, 1766(f)(3)(B)) and section 4(b)(1)(B) of the Child Nutrition Act of 1966 (42 U.S.C. 1773(b)(1)(B)).

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–15893 Filed 7–25–22; 8:45 am]

BILLING CODE 3410–30–C

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

National School Lunch, Special Milk, and School Breakfast Programs, National Average Payments/Maximum Reimbursement Rates

AGENCY: Food and Nutrition Service, Agriculture (USDA).

ACTION: Notice.

SUMMARY: This Notice announces the annual adjustments to the national average payments, the amount of money the Federal Government provides States for lunches, afterschool snacks, and breakfasts served to children

participating in the National School Lunch and School Breakfast Programs; to the maximum reimbursement rates, the maximum per lunch rate from Federal funds that a State can provide a school food authority for lunches served to children participating in the National School Lunch Program; and to the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. The annual payments and rates adjustments for the National School Lunch and School Breakfast Programs reflect changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers. The annual rate adjustment for the Special Milk Program reflects changes in the Producer Price Index for Fluid Milk Products. Further adjustments are made to these rates to reflect higher costs of providing meals in Alaska, Guam, Hawaii, Puerto Rico, and the Virgin Islands. The payments and rates are prescribed on an annual basis each July. Overall, reimbursement rates this year for the National School Lunch, Breakfast Programs and the Special Milk Program increased compared to last year.

DATES: These rates are effective from July 1, 2022 through June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Penny Burke, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, United States Department of Agriculture, 1320 Braddock Place, Suite 401, Alexandria, VA 22314, 303–844–0357.

SUPPLEMENTARY INFORMATION:

Temporary Adjustments Authorized Under the Keep Kids Fed Act of 2022

School meal operators face continued challenges related to the COVID–19 pandemic. To help alleviate some of those challenges, temporary additional funding for school lunch and school breakfast has been authorized under Section 2 of the Keep Kids Fed Act of 2022 (Pub. L. 117–158). This temporary funding will provide an additional reimbursement in the amount of 40 cents for each lunch served under the school lunch program authorized under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751), and an additional reimbursement in the amount of 15 cents for each breakfast served under the breakfast program established by section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773). These additional reimbursement amounts shall only be available for the school year beginning July 1, 2022 and ending on June 30, 2023.

Background

Special Milk Program for Children—Pursuant to section 3 of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1772), the Department announces the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. This rate is adjusted annually to reflect changes in the Producer Price Index for Fluid Milk Products, published by the Bureau of Labor Statistics of the Department of Labor.

National School Lunch and School Breakfast Programs—Pursuant to sections 11 and 17A of the Richard B. Russell National School Lunch Act, (42 U.S.C. 1759a and 1766a), and section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773), the Department annually announces the adjustments to the National Average Payment Factors and to the maximum Federal reimbursement rates for lunches and afterschool snacks served to children participating in the National School Lunch Program and breakfasts served to children participating in the School Breakfast Program. Adjustments are prescribed each July 1, based on changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the Department of Labor.

Lunch Payment Levels—Section 4 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753) provides general cash for food assistance payments to States to assist schools in purchasing food. The Richard B. Russell National School Lunch Act provides two different section 4 payment levels for lunches served under the National School Lunch Program. The lower payment level applies to lunches served by school food authorities in which less than 60 percent of the lunches served in the school lunch program during the second preceding school year were served free or at a reduced price. The higher payment level applies to lunches served by school food authorities in which 60 percent or more of the lunches served during the second preceding school year were served free or at a reduced price.

To supplement these section 4 payments, section 11 of the Richard B. Russell National School Lunch Act (42 U.S.C.1759(a)) provides special cash assistance payments to aid schools in providing free and reduced price lunches. The section 11 National Average Payment Factor for each reduced price lunch served is set at 40 cents less than the factor for each free lunch.

As authorized under sections 8 and 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1757 and 1759a), maximum reimbursement rates for each type of lunch are prescribed by the Department in this Notice. These maximum rates are to ensure equitable disbursement of Federal funds to school food authorities.

Performance-Based Reimbursement—In addition to the funding mentioned above, school food authorities certified as meeting the meal pattern and nutrition standard requirements set forth in 7 CFR parts 210 and 220 are eligible to receive performance-based cash assistance for each reimbursable lunch served (an additional eight cents per lunch available beginning July 1, 2022 and adjusted annually thereafter).

Afterschool Snack Payments in Afterschool Care Programs—Section 17A of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766a) establishes National Average Payments for free, reduced price and paid afterschool snacks as part of the National School Lunch Program.

Breakfast Payment Factors—Section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) establishes National Average Payment Factors for free, reduced price, and paid breakfasts served under the School Breakfast Program and additional payments for free and reduced price breakfasts served in schools determined to be in ''severe need'' because they serve a high percentage of needy children.

Adjusted Payments

The following specific section 4, section 11, and section 17A National Average Payment Factors and maximum reimbursement rates for lunch, the afterschool snack rates, and the breakfast rates are in effect from July 1, 2022 through June 30, 2023. Due to a higher cost of living, the average payments and maximum reimbursements for Alaska, Guam, Hawaii, Puerto Rico, and the Virgin Islands are higher than those for all other States. The District of Columbia uses figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which schools receive as additional assistance for each meal served to participants under the Program. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

Adjustments to the national average payment rates for all lunches served

under the National School Lunch Program, breakfasts served under the School Breakfast Program, and afterschool snacks served under the National School Lunch Program are rounded down to the nearest whole cent.

In addition to the adjustments to the national average payment rates, beginning July 1, 2022 and ending June 30, 2023, Congress has authorized, under the Keep Kids Fed Act of 2022 (Pub. L. 117–158), an additional temporary 40 cents reimbursement for each lunch served under the National School Lunch Program and an additional temporary 15 cents reimbursement for each breakfast served under the School Breakfast Program.

Special Milk Program Payments

For the period July 1, 2022 through June 30, 2023, the rate of reimbursement for a half-pint of milk served to a non-needy child in a school or institution that participates in the Special Milk Program is 27.00 cents reflecting an increase of 5 cents from the School Year (SY) 2021–2022 level. This change is based on the 22.74 percent increase in the Producer Price Index for Fluid Milk Products from May 2021 to May 2022.

As a reminder, schools or institutions with pricing programs that elect to serve milk free to eligible children continue to receive the average cost of a half-pint of milk (the total cost of all milk purchased during the claim period divided by the total number of purchased half-pints) for each half-pint served to an eligible child.

National School Lunch Program Payments (Including Temporary Increases Authorized by the Keep Kids Fed Act Which Expire on June 30, 2023)

Overall, payments for the National School Lunch Program and the Afterschool Snack Program increased from last year's payments due to additional funds for lunch reimbursement made available under the Keep Kids Fed Act of 2022 (P.L. 117–158) and a 7.40 percent increase in the national average payment rates for schools and residential child care institutions for the period July 1, 2022 through June 30, 2023 in the Consumer Price Index for All Urban Consumers for the Food Away From Home series during the 12-month period May 2021 to May 2022 (from a level of 303.481 in May 2021, as previously published in the **Federal Register**, to 325.952 in May 2022).

These changes are reflected below.

Section 4 National Average Payment Factors—In school food authorities that served less than 60 percent free and reduced price lunches in SY 2020–2021, the payments for meals served are: *Contiguous States*—paid rate—77 cents (42 cents increase from the SY 2021—2022 level), free and reduced price rate—77 cents (42 cents increase), maximum rate—85 cents (42 cents increase); *Alaska*—paid rate—1 dollar 1 cents (44 cents increase), free and reduced price rate—1 dollar 1 cents (44 cents increase), maximum rate—1 dollar 11 cents (43 cents increase); *Guam, Hawaii, Puerto Rico, and the Virgin Islands*—paid rate—84 cents (43 cents increase), free and reduced price rate—84 cents (43 cents increase), maximum rate—92 cents (43 cents increase).

In school food authorities that served 60 percent or more free and reduced price lunches in School Year 2020—2021, payments are: *Contiguous States*—paid rate—79 cents (42 cents increase from the SY 2021—2022 level), free and reduced price rate—79 cents (42 cents increase), maximum rate—85 cents (42 cents increase); *Alaska*—paid rate—1 dollar 3 cents (44 cents increase), free and reduced price rate—1 dollar 3 cents (44 cents increase), maximum rate—1 dollar 11 cents (43 cents increase); *Guam, Hawaii, Puerto Rico and the Virgin Islands*—paid rate—86 cents (43 cents increase), free and reduced price rate—86 cents (43 cents increase), maximum rate—92 cents (43 cents increase).

School food authorities certified to receive the performance-based cash assistance will receive an additional 8 cents (adjusted annually) added to the above amounts as part of their section 4 payments.

Section 11 National Average Payment Factors—Contiguous States—free lunch—3 dollars and 56 cents (25 cents increase from the SY 2021—2022 level), reduced price lunch—3 dollars and 16 cents (25 cents increase); *Alaska*—free lunch—5 dollars and 76 cents (39 cents increase), reduced price lunch—5 dollars and 36 cents (39 cents increase); *Guam, Hawaii, Puerto Rico and the Virgin Islands*—free lunch—4 dollars and 16 cents (29 cents increase), reduced price lunch—3 dollars and 76 cents (29 cents increase).

Afterschool Snacks in Afterschool Care Programs—The payments are: *Contiguous States*—free snack—1 dollar and 8 cents (8 cents increase from the SY 2021—2022 level), reduced price snack—54 cents (4 cents increase), paid snack—9 cents (no increase); *Alaska*—free snack –1 dollar and 75 cents (12 cents increase), reduced price snack—87 cents (6 cents increase), paid snack—16 cents (2 cents increase); *Guam, Hawaii, Puerto Rico and the Virgin Islands*—free snack—1 dollar and 26 cents (9 cents increase), reduced price snack—63 cents (5 cent increase), paid snack—11 cents (1 cent increase).

School Breakfast Program Payments (Including Temporary Increases Authorized by the Keep Kids Fed Act Which Expire on June 30, 2023)

Overall, payments for the National School Breakfast Program either remained the same or increased from last year's payments due to additional funds for breakfast reimbursement made available under the Keep Kids Fed Act of 2022 (Pub. L. 117–158) and a 7.40 percent increase in the national average payment rates for schools and residential child care institutions for the period July 1, 2022 through June 30, 2023 in the Consumer Price Index for All Urban Consumers in the Food Away from Home series during the 12-month period May 2021 to May 2022 (from a level of 303.481 in May 2021, as previously published in the **Federal Register**, to 325.952 in May 2022).

These changes are reflected below.

For schools ''not in severe need'' the payments are: *Contiguous States*—free breakfast—2 dollars and 26 cents (29 cents increase from the SY 2021—2022 level), reduced price breakfast—1 dollar and 96 cents (29 cents increase), paid breakfast—50 cents (17 cent increase); *Alaska*—free breakfast—3 dollars and 53 cents (38 cents increase), reduced price breakfast—3 dollars and 23 cents (38 cents increase), paid breakfast—69 cents (19 cent increase); *Guam, Hawaii, Puerto Rico and the Virgin Islands*—free breakfast—2 dollars and 61 cents (32 cents increase), reduced price breakfast—2 dollars and 31 cents (32 cents increase), paid breakfast—55 cents (17 cents increase).

For schools in ''severe need'' the payments are: *Contiguous States*—free breakfast—2 dollars and 67 cents (32 cents increase from the SY 2021—2022 level), reduced price breakfast—2 dollars and 37 cents (32 cents increase), paid breakfast—50 cents (17 cent increase); *Alaska*—free breakfast—4 dollars and 21 cents (43 cents increase), reduced price breakfast—3 dollars and 91 cents (43 cents increase), paid breakfast—69 cents (19 cent increase); *Guam, Hawaii, Puerto Rico and the Virgin Islands*—free breakfast—3 dollars and 09 cents (35 cents increase), reduced price breakfast—2 dollars and 79 cents (35 cents increase), paid breakfast—55 cents (17 cent increase).

Payment Chart Including Additional Temporary Reimbursement The following chart illustrates the temporary increased reimbursement for breakfast and lunch as authorized under the Keep Kids Fed Act of 2022 (Pub. L. 117–158).

Lunch National Average Payment Factors have sections 4 and 11 already combined to indicate the per lunch amount; the maximum lunch reimbursement rates and the breakfast National Average Payment Factors including severe need schools. All amounts are expressed in dollars or fractions thereof. The payment factors and reimbursement rates used for the District of Columbia are those specified for the contiguous States.

BILLING CODE 3410–30–P

Temporary Reimbursement Payment Chart

SCHOOL PROGRAMS

MEAL, SNACK AND MILK PAYMENTS TO STATES AND SCHOOL FOOD AUTHORITIES

Expressed in Dollars or Fractions Thereof

Effective for the School Year Beginning July 1, 2022 through June 30, 2023

NATIONAL SCHOOL LUNCH PROGRAM[1,3]		LESS THAN 60%	LESS THAN 60% + 8 cents[2]	60% OR MORE	60% or MORE + 8 cents[2]	MAXIMUM RATE	MAXIMUM RATE + 8 cents[2]
CONTIGUOUS STATES	PAID	0.77	0.85	0.79	0.87	0.85	0.93
	REDUCED	3.93	4.01	3.95	4.03	4.10	4.18
	FREE	4.33	4.41	4.35	4.43	4.50	4.58
ALASKA	PAID	1.01	1.09	1.03	1.11	1.11	1.19
	REDUCED	6.37	6.45	6.39	6.47	6.62	6.70
	FREE	6.77	6.85	6.79	6.87	7.02	7.10
GUAM, HAWAII, PUERTO RICO and VIRGIN ISLANDS	PAID	0.84	0.92	0.86	0.94	0.92	1.00
	REDUCED	4.60	4.68	4.62	4.70	4.79	4.87
	FREE	5.00	5.08	5.02	5.10	5.19	5.27

SCHOOL BREAKFAST PROGRAM[3]		NON-SEVERE NEED	SEVERE NEED
Temporary Additional Breakfast Reimbursement			
CONTIGUOUS STATES	PAID	0.50	0.50
	REDUCED PRICE	1.96	2.37
	FREE	2.26	2.67
ALASKA	PAID	0.69	0.69
	REDUCED PRICE	3.23	3.91
	FREE	3.53	4.21
GUAM, HAWAII, PUERTO RICO and VIRGIN ISLANDS	PAID	0.55	0.55
	REDUCED PRICE	2.31	2.79
	FREE	2.61	3.09

SPECIAL MILK PROGRAM	ALL MILK	PAID MILK	FREE MILK
PRICING PROGRAMS WITHOUT FREE OPTION	0.2700	N/A	N/A
PRICING PROGRAMS WITH FREE OPTION	N/A	0.2700	Average Cost Per 1/2 Pint of
NONPRICING PROGRAMS	0.2700	N/A	N/A

AFTERSCHOOL SNACKS SERVED IN AFTERSCHOOL CARE PROGRAMS		
CONTIGUOUS STATES	PAID	0.09
	REDUCED PRICE	0.54
	FREE	1.08
ALASKA	PAID	0.16
	REDUCED PRICE	0.87
	FREE	1.75
GUAM, HAWAII, PUERTO RICO and VIRGIN ISLANDS	PAID	0.11
	REDUCED PRICE	0.63
	FREE	1.26

[1] Payment listed for Free and Reduced Price Lunches include both section 4 and section 11 funds

[2] Performance-based cash reimbursement (adjusted annually for inflation)

[3] The Keep Kids Fed Act of 2022 provides an additional 40 cents for each lunch served and allows an additional 15 cents for each breakfast served for the school year starting July 1, 2022 ending on June 30, 2023.

BILLING CODE 3410–30–C

Base Payment Chart (Excludes The Temporary Increases Authorized by Keep Kids Fed Act of 2022)

The following chart illustrates the lunch National Average Payment Factors with the sections 4 and 11 already combined to indicate the per lunch amount; the maximum lunch reimbursement rates; the reimbursement rates for afterschool snacks served in afterschool care programs; the breakfast National Average Payment Factors including severe need schools; and the milk reimbursement rate. All amounts are expressed in dollars or fractions thereof. The payment factors and reimbursement rates used for the District of Columbia are those specified for the contiguous States.

BILLING CODE 3410–30–P

Base Payment Chart[1]

SCHOOL PROGRAMS

MEAL, SNACK AND MILK PAYMENTS TO STATES AND SCHOOL FOOD AUTHORITIES

Expressed in Dollars or Fractions Thereof

Effective from: July 1, 2022 - June 30, 2023

NATIONAL SCHOOL LUNCH PROGRAM[2]		LESS THAN 60%	LESS THAN 60% + 8 cents[3]	60% OR MORE	60% or MORE + 8 cents[3]	MAXIMUM RATE	MAXIMUM RATE + 8 cents[3]
CONTIGUOUS STATES	PAID	0.37	0.45	0.39	0.47	0.45	0.53
	REDUCED PRICE	3.53	3.61	3.55	3.63	3.70	3.78
	FREE	3.93	4.01	3.95	4.03	4.10	4.18
ALASKA	PAID	0.61	0.69	0.63	0.71	0.71	0.79
	REDUCED PRICE	5.97	6.05	5.99	6.07	6.22	6.30
	FREE	6.37	6.45	6.39	6.47	6.62	6.70
GUAM, HAWAII, PUERTO RICO and VIRGIN ISLANDS	PAID	0.44	0.52	0.46	0.54	0.52	0.60
	REDUCED PRICE	4.20	4.28	4.22	4.30	4.39	4.47
	FREE	4.60	4.68	4.62	4.70	4.79	4.87

SCHOOL BREAKFAST PROGRAM		NON-SEVERE NEED	SEVERE NEED
CONTIGUOUS STATES	PAID	0.35	0.35
	REDUCED PRICE	1.81	2.22
	FREE	2.11	2.52
ALASKA	PAID	0.54	0.54
	REDUCED PRICE	3.08	3.76
	FREE	3.38	4.06
GUAM, HAWAII, PUERTO RICO and VIRGIN ISLANDS	PAID	0.40	0.40
	REDUCED PRICE	2.16	2.64
	FREE	2.46	2.94

SPECIAL MILK PROGRAM	ALL MILK	PAID MILK	FREE MILK
PRICING PROGRAMS WITHOUT FREE OPTION	0.2700	N/A	N/A
PRICING PROGRAMS WITH FREE OPTION	N/A	0.2700	Average Cost Per 1/2 Pint of Milk
NONPRICING PROGRAMS	0.2700	N/A	N/A

AFTERSCHOOL SNACKS SERVED IN AFTERSCHOOL CARE PROGRAMS		
CONTIGUOUS STATES	PAID	0.09
	REDUCED PRICE	0.54
	FREE	1.08
ALASKA	PAID	0.16
	REDUCED PRICE	0.87
	FREE	1.75
GUAM, HAWAII, PUERTO RICO and VIRGIN ISLANDS	PAID	0.11
	REDUCED PRICE	0.63
	FREE	1.26

[1]These rates **do not** include the increased reimbursement authorized by the Keep Kids Fed Act

[2]Payment listed for Free and Reduced Price Lunches include both section 4 and section 11 funds

[3]Performance-based cash reimbursement (adjusted annually for inflation)

BILLING CODE 3410–30–C

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. This notice has

been determined to be exempt under Executive Order 12866.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

National School Lunch, School Breakfast, and Special Milk Programs are listed in the Catalog of Federal Domestic Assistance under No. 10.555, No. 10.553, and No. 10.556, respectively, and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials (See 2 CFR 415.3–415.6).

Authority: Sections 4, 8, 11, and 17A of the Richard B. Russell National School Lunch Act, as amended, (42 U.S.C. 1753, 1757, 1759a, 1766a) and sections 3 and 4(b) of the Child Nutrition Act, as amended, (42 U.S.C. 1772 and 42 U.S.C. 1773(b)).

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–15892 Filed 7–25–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Generic Clearance for Census Bureau Field Tests and Evaluations

AGENCY: Census Bureau, Commerce.

ACTION: Notice of Information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed extension of the Generic Clearance for Census Bureau Field Tests and Evaluations, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before September 26, 2022.

ADDRESSES: Interested persons are invited to submit written comments by email to Jennifer Hunter Childs (*jennifer.hunter.childs@census.gov*). Please reference Generic Clearance for Census Bureau Field Tests and Evaluations in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2022–0013, to the Federal e-Rulemaking Portal: *https://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *https://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Jennifer Hunter Childs, Assistant Center Chief, Emerging Methods and Applications, Center for Behavioral Science Methods, (202) 603–4827, *jennifer.hunter.childs@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau plans to request an extension of the current OMB approval to conduct a series of studies to research and evaluate how to improve data collection activities for data collection programs at the Census Bureau. These studies will explore how the Census Bureau can improve efficiency, data quality, and response rates and reduce respondent burden in future census and survey operations, evaluations and experiments.

This information collection will operate as a generic clearance. The estimated number of respondents and annual reporting hours requested cover both the known and yet to be determined tests. A generic clearance is needed for these tests because though each share similar methodology, the exact number of tests and the explicit details of each test to be performed has yet to be determined. Once information collection plans are defined, they will be submitted on an individual basis in order to keep OMB informed as these tests progress.

The Census Bureau plans to test the use of new and improved data collection techniques for self-enumeration and interviewer data-collection tasks surrounding and following the ongoing census and survey operations. The research and evaluation may include: developing alternative enumeration or follow-up questionnaires; usability issues; conducting interviews or debriefings; and non-English language training and interviews. To study enumeration, the Census Bureau may conduct the enumeration directly with a household member or knowledgeable respondent. The questions asked in these studies will be typical census or survey questions and questions related to that content, along with potential attitudinal and satisfaction debriefing questions.

II. Method of Collection

The information will be collected through observations, self-response, face-face interviews, and/or telephone interviews.

III. Data

OMB Control Number: 0607–0971.

Form Number(s): Not yet determined.

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

Affected Public: Individuals or households, businesses or other for profit, farms.

Estimated Number of Respondents: 100,000 per year.

Estimated Time per Response: 25 minutes.

Estimated Total Annual Burden Hours: 41,667 hours annually.

Estimated Total Annual Cost to Public: There is no cost to the respondent other than time to answer the information request.

Respondent's Obligation: Voluntary or Mandatory, depending on cited authority.

Legal Authority: Data collection for this project is authorized under the authorizing legislation for the questionnaire being tested. This may be Title 13, Sections 131, 141, 161, 181, 182, 193, and 301 for Census Bureau sponsored surveys, and Title 13 and 15 for surveys sponsored by other Federal agencies. We do not now know what other titles will be referenced, since we do not know what survey questionnaires will be pretested during the course of the clearance.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed

information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–15982 Filed 7–25–22; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; National Security and Critical Technology Assessments of the U.S. Industrial Base

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on April 4, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Industry and Security, Commerce.

Title: National Security and Critical Technology Assessments of the U.S. Industrial Base.

OMB Control Number: 0694–0119.

Form Number(s): None.

Type of Request: Regular submission, revision, and extension of a current information collection.

Number of Respondents: 28,000.

Average Hours per Response: 8 to 14 hours.

Burden Hours: 308,000.

Needs and Uses: The Bureau of Industry and Security (BIS) conducts surveys and assessments of critical U.S. industrial sectors and technologies. Undertaken at the request of various policy, research and development (R&D), and program and planning organizations within the Department of Defense and the Armed Services, Department of Homeland Security (DHS), NASA and other agencies, BIS research, data collection and analysis provide needed information to benchmark industry performance and raise awareness of diminishing manufacturing capabilities.

Affected Public: Business or other for-profit organizations.

Frequency: On Occasion.

Respondent's Obligation: Mandatory.

Legal Authority: Section 705 of the Defense Production Act of 1950, as amended, Executive Orders 12656 and 13603.

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

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0694–0119.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–16015 Filed 7–25–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–871]

Finished Carbon Steel Flanges From India: Final Results of Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 6, 2022, the U.S. Department of Commerce (Commerce) published its notice of initiation and preliminary results of a changed circumstances review (CCR) of the antidumping duty (AD) order on finished carbon steel flanges (flanges) from India. For these final results, Commerce finds that BFN Forgings Private Limited (BFN) is the successor-in-interest to Bebitz Flanges Works Private Limited (Bebitz) and should be assigned the same AD cash deposit rate for purposes of determining AD liability.

DATES: Applicable July 26, 2022.

FOR FURTHER INFORMATION CONTACT: James R. Hepburn or Fred Baker, 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) 482–4885 or (202) 482–2924, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 14, 2022, BFN requested that Commerce conduct an expedited CCR of the AD order on flanges from India [1] to find that BFN is the successor-in-interest to Bebitz.[2] On June 6, 2022, Commerce initiated a CCR and preliminarily determined that BFN is the successor-in-interest to Bebitz.[3] In the *Initiation and Preliminary Results,* we provided all interested parties with an opportunity to comment.[4] We received no comments from any interested party.

[1] *See Finished Carbon Steel Flanges from India and Italy: Antidumping Duty Orders,* 82 FR 40136 (August 24, 2017) (*Order*).

[2] *See* BFN's Letter, ''Finished Carbon Steel Flanges from India: Request for an Expedited Successor-in-Interest Changed Circumstances Review,'' dated April 14, 2022.

[3] *See Finished Carbon Steel Flanges from India: Notice of Initiation and Preliminary Results of Changed Circumstances Review,* 87 FR 34251 (June 6, 2022) (*Initiation and Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[4] *Id.,* 87 FR at 34252.

Scope of the Order

The merchandise covered by the *Order* is flanges from India. The merchandise subject to the *Order* is currently classified under subheadings 7307.91.5010 and 7307.91.5050 of the Harmonized Tariff Schedule of the United States (HTSUS). They may also be entered under HTSUS subheadings 7307.91.5030 and 7307.91.5070. The HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope is dispositive.[5]

Final Results of Changed Circumstances Review

Because the record contains no information or evidence that calls into question the *Initiation and Preliminary Results,* and because we received no comments from interested parties to the contrary, for the reasons stated in the *Initiation and Preliminary Results,*[6] Commerce finds that BFN is the successor-in-interest to Bebitz.

Instructions to U.S. Customs and Border Protection

As a result of these final results and consistent with established practice, we find that, as the successor-in-interest to Bebitz, entries of flanges from India produced and/or exported by BFN should be subject to the cash deposit rate previously assigned to Bebitz. Commerce will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced and/or exported by BFN and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at 0.00 percent, which is the current AD cash deposit rate in effect for subject merchandise produced and/or exported by Bebitz.[7] This cash deposit rate shall remain in effect until further notice.

Administrative Protective Order

This notice serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(b)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.216(e), 351.221(b), and 351.221(c)(3).

Dated: July 20, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–16027 Filed 7–25–22; 8:45 am]

BILLING CODE 3510–DS–P

[5] For the full scope language, *see* the *Initiation and Preliminary Results* PDM at 2–3.

[6] For a complete discussion of the information that BFI provided, including business proprietary information, and Commerce's complete successor-in-interest analysis, *see* the *Initiation and Preliminary Results* PDM.

[7] *See Finished Carbon Steel Flanges from India: Final Results of Antidumping Duty Administrative Review; 2019–2020,* 87 FR 13703, 13704 (March 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Ruling Applications Filed in Antidumping and Countervailing Duty Proceedings

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) received scope ruling applications, requesting that scope inquiries be conducted to determine whether identified products are covered by the scope of antidumping duty (AD) and/or countervailing duty (CVD) orders and that Commerce issue scope rulings pursuant to those inquiries. In accordance with Commerce's regulations, we are notifying the public of the filing of the scope ruling applications listed below in the month of June 2022.

DATES: Applicable July 26, 2022.

FOR FURTHER INFORMATION CONTACT: Terri Monroe, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–1384.

Notice of Scope Ruling Applications: In accordance with 19 CFR 351.225(d)(3), we are notifying the public of the following scope ruling applications related to AD and CVD orders and findings filed in or around the month of June 2022. This notification includes, for each scope application: (1) identification of the AD and/or CVD orders at issue (19 CFR 351.225(c)(1)); (2) concise public descriptions of the products at issue, including the physical characteristics (including chemical, dimensional and technical characteristics) of the products (19 CFR 351.225(c)(2)(ii)); (3) the countries where the products are produced and the countries from where the products are exported (19 CFR 351.225(c)(2)(i)(B)); (4) the full names of the applicants; and (5) the dates that the scope applications were filed with Commerce and the name of the scope segment where the scope applications can be found on Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS).[1] This notice does not include applications which have been rejected and not properly resubmitted. The scope ruling applications listed below are available on ACCESS, at *https://access.trade.gov.*

Scope Ruling Applications

Aluminum Extrusions from the People's Republic of China (China) (A–570–967/C–570–968); aluminum pair ramps;[2] produced in and exported from China; submitted by Central Purchasing, LLC dba Harbor Freight Tools (Harbor Freight); June 1, 2022; ACCESS scope segment ''Harbor Freight Aluminum Pair Ramps.''

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules (Solar Cells) from China (A–570–979/C–570–980); Power Solar 3-Port 100W solar panel (model A2431) (3 Port 100W Solar Panel);[3] produced in

[1] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300, 52316 (September 20, 2021) (''It is our expectation that the **Federal Register** list will include, where appropriate, for each scope application the following data: (1) identification of the AD and/or CVD orders at issue; (2) a concise public summary of the product's description, including the physical characteristics (including chemical, dimensional and technical characteristics) of the product; (3) the country(ies) where the product is produced and the country from where the product is exported; (4) the full name of the applicant; and (5) the date that the scope application was filed with Commerce.'').

[2] The products subject to Harbor Freight's request include aluminum pair ramps with bolted-on polyester straps with S-hooks and ratchets, produced in and exported from China under HTSUS code 8708.29.5060. The dimensions and loading capacities of the aluminum pair ramps are approx. 12 x 90 inches and 3,000 pounds, 13 x 77 inches and 1,250 pounds, and 12 x 90 inches and 1,500 pounds.

[3] Anker's PowerSolar 3-Port 100W solar panel, Model A2431, is a foldable outdoor panel for charging cell phones and other portable electronic devices. The panel provides total maximum output of 100 Watts. The solar panel is laminated and encased in sewn fabric. The unfolded panel dimensions are approx. 57.7 x 20.7 x 1.8 inches (1,446 x 525 x 45 mm). The dimensions of the retracted case are approx. 20.7 x 18.5 x 3.3 inches (525 x 470 x 85 mm). The unit weighs approx. 11.0 lbs (5 kg). The solar cells have visible parallel grid collector metallic wire lines every 1 mm across each solar panel. The unit has two storage pockets for

and exported from China; submitted by Anker Innovations Limited (Anker); June 2, 2022; ACCESS scope segment ''Anker 3 Port 100W Solar Panel.''

Solar Cells from China (A–570–979/C–570–980); Renogy brand off-grid solar panels;[4] produced in and exported from China; submitted by RNG International Inc. (RNG); June 10, 2022; ACCESS scope segment ''RNG International.''

Notification to Interested Parties

This list of scope ruling applications is not an identification of scope inquiries that have been initiated. In accordance with 19 CFR 351.225(d)(1), if Commerce has not rejected a scope ruling application nor initiated the scope inquiry within 30 days after the filing of the application, the application will be deemed accepted and a scope inquiry will be deemed initiated the following day—day 31.[5] Commerce's practice generally dictates that where a deadline falls on a weekend, Federal holiday, or other non-business day, the appropriate deadline is the next business day.[6] Accordingly, if the 30th day after the filing of the application falls on a non-business day, the next business day will be considered the ''updated'' 30th day, and if the application is not rejected or a scope inquiry initiated by or on that particular business day, the application will be deemed accepted and a scope inquiry will be deemed initiated on the next business day which follows the ''updated'' 30th day.[7]

In accordance with 19 CFR 351.225(m)(2), if there are companion AD and CVD orders covering the same merchandise from the same country of origin, the scope inquiry will be conducted on the record of the AD proceeding. Further, please note that pursuant to 19 CFR 351.225(m)(1), Commerce may either apply a scope ruling to all products from the same country with the same relevant physical characteristics, (including chemical, dimensional, and technical characteristics) as the product at issue, on a country-wide basis, regardless of the producer, exporter, or importer of those products, or on a company-specific basis.

For further information on procedures for filing information with Commerce through ACCESS and participating in scope inquiries, please refer to the Filing Instructions section of the Scope Ruling Application Guide, at *https://access.trade.gov/help/Scope_Ruling_Guidance.pdf.* Interested parties, apart from the scope ruling applicant, who wish to participate in a scope inquiry and be added to the public service list for that segment of the proceeding must file an entry of appearance in accordance with 19 CFR 351.103(d)(1) and 19 CFR 351.225(n)(4). Interested parties are advised to refer to the case segment in ACCESS as well as 19 CFR 351.225(f) for further information on the scope inquiry procedures, including the timelines for the submission of comments.

Please note that this notice of scope ruling applications filed in AD and CVD proceedings may be published before any potential initiation, or after the initiation, of a given scope inquiry based on a scope ruling application identified in this notice. Therefore, please refer to the case segment on ACCESS to determine whether a scope ruling application has been accepted or rejected and whether a scope inquiry has been initiated.

Interested parties who wish to be served scope ruling applications for a particular AD or CVD order may file a request to be included on the annual inquiry service list during the anniversary month of the publication of the AD or CVD order in accordance with 19 CFR 351.225(n) and Commerce's procedures.[8]

Interested parties are invited to comment on the completeness of this monthly list of scope ruling applications received by Commerce. Any comments should be submitted to James Maeder, Deputy Assistant Secretary for AD/CVD Operations, Enforcement and Compliance, International Trade Administration, via email to *CommerceCLU@trade.gov.*

This notice of scope ruling applications filed in AD and CVD proceedings is published in accordance with 19 CFR 351.225(d)(3).

Dated: July 20, 2022.

Scot Fullerton,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2022–16010 Filed 7–25–22; 8:45 am]

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storing charging accessories and other devices. The unit's charging is provided via a Female USB–A wire and port.

[4] The products subject to this scope ruling request are Renogy brand off-grid solar panels. Models KIT–STCS100D–NC, RNG–100D–SS, and KIT–STCS100D–VOY20 are off-grid 100 watt solar panels with regular mono crystalline solar cells (100w panel). Models 50D–SS and RKIT50DST are off-grid 50 watt solar panels (50w panel). Each model has a glass cover and has a power output of 100 watts or less. Additionally, each panel has a surface area under 8,000 cm2. The 100w panel's surface area is 6420cm2 and the 50w panel's surface area is 2960cm2. None of the panels have built-in inverters and each one contains a permanently connected wire that terminates in a two-port rectangular connector with two pins in square housings of different colors. Each panel also includes visible parallel grid collector metallic wire lines every 1.4 millimeters across each solar cell. Model RNG–100DB–H is an off-grid 100 watt flexible solar panel with regular mono crystalline solar cells that does not contain a glass cover (flexible panel). The flexible panel has a total power output of 100 watts or less and a maximum surface area of 6,655.74 cm2. The flexible panel is not equipped with a built-in inverter. The flexible panel includes visible parallel grid collector metallic wire lines every 1 millimeters across each solar cell. Additionally, the flexible panel is encased in a laminated material without stitching. Each model is packaged in individual retail boxes with warranty cards and expanded polypropylene, or EPP, corner protectors, in its condition as imported into the United States.

[5] In accordance with 19 CFR 351.225(d)(2), within 30 days after the filing of a scope ruling application, if Commerce determines that it intends to address the scope issue raised in the application in another segment of the proceeding (such as a circumvention inquiry under 19 CFR 351.226 or a covered merchandise inquiry under 19 CFR 351.227), it will notify the applicant that it will not initiate a scope inquiry, but will instead determine if the product is covered by the scope at issue in that alternative segment.

[6] *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

[7] This structure maintains the intent of the applicable regulation, 19 CFR 351.225(d)(1), to allow day 30 and day 31 to be separate business days.

[8] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC070]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Office of Naval Research's Arctic Research Activities in the Beaufort and Chukchi Seas (Year 5)

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from Office of Naval Research (ONR) for authorization to take marine mammals incidental to Arctic Research Activities (ARA) in the Beaufort Sea and eastern Chukchi Sea. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified

activities. NMFS is also requesting comments on a possible one-time, one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision. The ONR's activities are considered military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act for Fiscal Year 2004 (2004 NDAA).

DATES: Comments and information must be received no later than August 25, 2022.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to *ITP.taylor@noaa.gov*.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Jessica Taylor, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities*. In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth.

The 2004 NDAA (Pub. L. 108–136) removed the ''small numbers'' and ''specified geographical region'' limitations indicated above and amended the definition of ''harassment'' as applied to a ''military readiness activity.'' The activity for which incidental take of marine mammals is being requested addressed here qualifies as a military readiness activity. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

In 2018, the U.S. Navy prepared an Overseas Environmental Assessment (OEA; referred to as an EA in this document) analyzing the project. Prior to issuing the IHA for the first year of this project, NMFS reviewed the 2018 EA and the public comments received, determined that a separate NEPA analysis was not necessary, and subsequently adopted the document and issued a NMFS Finding of No Significant Impact (FONSI) in support of the issuance of an IHA (83 FR 48799; September 27, 2018).

In 2019, the U.S. Navy prepared a supplemental EA. Prior to issuing the IHA in 2019, NMFS reviewed the supplemental EA and the public comments received, determined that a separate NEPA analysis was not necessary, and subsequently adopted the document and issued a NMFS FONSI in support of the issuance of an IHA (84 FR 50007; September 24, 2019).

In 2020, the U.S. Navy submitted a request for a renewal of the 2019 IHA. Prior to issuing the renewal IHA, NMFS reviewed ONR's application and determined that the proposed action was identical to that considered in the previous IHA. Because no significantly new circumstances or information relevant to any environmental concerns had been identified, NMFS determined that the preparation of a new or supplemental NEPA document was not necessary and relied on the supplement EA and FONSI from 2019 when issuing the renewal IHA in 2020 (85 FR 41560; July 10, 2020).

In 2021, the U.S. Navy submitted a request for an IHA for incidental take of marine mammals during continuation of ARA. NMFS reviewed the U.S. Navy's EA and determined it to be sufficient for taking into consideration the direct, indirect, and cumulative effects to the human environment resulting from continuation of the ARA. NMFS subsequently adopted that EA and signed a Finding of No Significant Impact (FONSI) (86 FR 54931, October 5, 2021).

Accordingly, NMFS preliminarily has determined to adopt the U.S. Navy's OEA for Office of Naval Research Arctic Research Activities in the Beaufort and Chukchi Seas 2022–2025, provided our independent evaluation of the document finds that it includes adequate information analyzing the effects on the human environment of issuing the IHA. NMFS is a not cooperating agency on the U.S. Navy's OEA.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On March 21, 2022, NMFS received a request from ONR for an IHA to take marine mammals incidental to ARA in the Beaufort and eastern Chukchi Seas. The application was deemed adequate and complete on June 30, 2022. ONR's request is for take of beluga whales (*Delphinapterus leucas*; two stocks) and ringed seals (*Pusa hispida hispida*) by Level B harassment. Neither ONR nor NMFS expect serious injury or mortality

to result from this activity and, therefore, an IHA is appropriate.

This proposed IHA would cover the fifth year of a larger project for which ONR obtained prior IHAs (83 FR 48799, September 27, 2018; 84 FR 50007, September 24, 2019; 85 FR 53333, August 28, 2020; 86 FR 54931, October 5, 2021) and may request take authorization for subsequent facets of the overall project. This IHA would be valid for a period of one year from the date of issuance (mid-September 2022 to mid- September 2023). The larger project supports the development of an under-ice navigation system under the ONR Arctic Mobile Observing System (AMOS) project. ONR has complied with all the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHAs (83 FR 48799, September 27, 2018; 84 FR 50007, September 24, 2019; 85 FR 53333, August 28, 2020; 86 FR 54931, October 5, 2021).

Description of Proposed Activity

Overview

ONR's ARA include scientific experiments to be conducted in support of the programs named above. Specifically, the project includes the Arctic Mobile Observing System (AMOS) experiments in the Beaufort and Chukchi Seas. Project activities involve acoustic testing and a multi-frequency navigation system concept test using left-behind active acoustic sources. More specifically, these experiments involve the deployment of moored, drifting, and ice-tethered active acoustic sources from the Research Vessel (R/V) Sikuliaq. Another vessel will be used to retrieve the acoustic sources. Underwater sound from the acoustic sources may result in Level B harassment of marine mammals.

Dates and Duration

This proposed action would occur from mid-September 2022 through mid-September 2023. The 2022 cruise would leave from Nome, Alaska on September 14, 2022 using the R/V *Sikuliaq* and involve 120 hours of active source testing. During this first cruise, several acoustic sources would be deployed from the ship. Some acoustic sources will be left behind to provide year-round observation of the Arctic environment. Gliders deployed during the September 2022 cruise may be recovered before the research vessel departs the study area or during a September 2023 cruise. Up to seven fixed acoustic navigation sources transmitting at 900 Hertz (Hz) would remain in place for a year. Drifting and moored oceanographic sensors would record environmental parameters throughout the year. Autonomous weather stations and ice mass balance buoys would also be deployed to record environmental measurements throughout the year (Table 1). The research vessel is planned to return to Nome, Alaska on October 28, 2022. ONR will apply for a renewal or separate IHA, as appropriate, for activities conducted during the planned September 2023 cruise.

During the scope of this proposed project, other activities may occur at different intervals that would assist ONR in meeting the scientific objectives of the various projects discussed above. However, these activities are designated as de minimis sources in ONR's 2022–2023 IHA application (consistent with analyses presented in support of previous Navy ONR IHAs), or would not produce sounds detectable by marine mammals (see discussion on de minimis sources below). These include the deployment of a Woods Hole Oceanographic Institution (WHOI) micromodem, acoustic Doppler current profilers (ADCP), and ice profilers (Table 2).

Geographic Region

This proposed action would occur across the U.S. Exclusive Economic Zone (EEZ) in both the Beaufort and Chukchi Seas, partially in the high seas north of Alaska, the Global Commons, and within a part of the Canadian EEZ (in which the appropriate permits would be obtained by the Navy) (Figure 1). The proposed action would primarily occur in the Beaufort Sea, but the analysis considers the drifting of active sources on buoys into the eastern portion of the Chukchi Sea. The closest point of the study area to the Alaska coast is 110 nm (204 km). The proposed study area is approximately 639,267 km^2.

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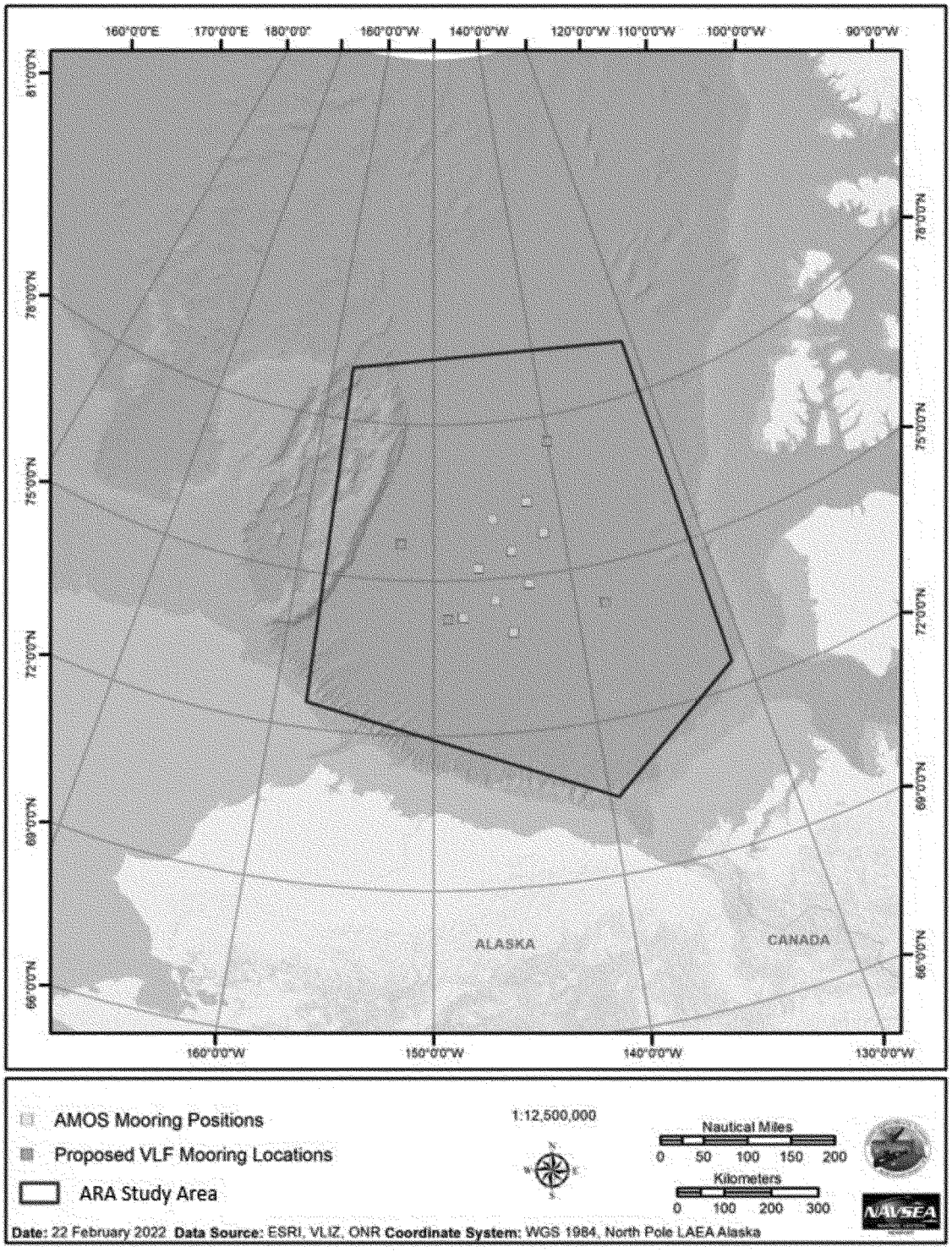

Figure 1. ONR ARA Study Area and Fixed Source Locations

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Detailed Description of Specific Activity

The ONR Arctic and Global Prediction Program supports two major projects: Stratified Ocean Dynamics of the Arctic (SODA) and AMOS. The SODA and AMOS projects have been previously discussed in association with previously issued IHAs (83 FR 40234, August 14, 2018; 84 FR 37240, July 31, 2019). However, only activities relating to the AMOS project will occur during the period covered by this proposed action.

The AMOS project constitutes the development of a new system involving very low (35 Hz)), low (900 Hz), and mid-frequency transmissions (10 kilohertz (kHz)). The AMOS project would utilize acoustic sources and receivers to provide a means of performing under-ice navigation for

gliders and unmanned underwater vehicles (UUVs). This would allow for the possibility of year-round scientific observations of the environment in the Arctic. As an environment that is particularly affected by climate change, year-round observations under a variety of ice conditions are required to study the effects of this changing environment for military readiness, as well as the implications of environmental change to humans and animals. Very-low frequency technology is important in extending the range of navigation systems. The technology also has the potential to allow for development and use of navigational systems that would not be heard by some marine mammal species, and therefore would be less impactful overall.

Active acoustic sources would be lowered from the cruise vessel while stationary, deployed on gliders and UUVs, or deployed on fixed AMOS moorings. This project would use groups of drifting buoys with sources and receivers communicating oceanographic information to a satellite in near real time. These sources would employ low-frequency transmissions only (900 Hz).

The proposed action would utilize non-impulsive acoustic sources, although not all sources will cause take of marine mammals. Any marine mammal takes would only arise from the operation of non-impulsive active sources. Although not currently planned, ice breaking could occur as part of this proposed action if a research vessel needs to return to the study area before the end of the IHA period to ensure scientific objectives are met. In this case, ice breaking could result in potential Level B harassment takes.

Below are descriptions of the equipment and platforms that would be deployed at different times during the proposed action.

Research Vessels

The R/V *Sikuliaq* would perform the research cruise in September 2022 and conduct testing of acoustic sources during the cruise, as well as leave sources behind to operate as a year-round navigation system observation. R/V *Sikuliaq* has a maximum speed of approximately 12 knots (6.2 m/s) with a cruising speed of 11 knots (5.7 m/s) (University of Alaska Fairbanks 2014). The R/V *Sikuliaq* is not an ice breaking ship, but an ice strengthened ship. It would not be icebreaking and therefore acoustic signatures of icebreaking for the R/V *Sikuliaq* are not relevant.

The ship to be used in September 2023 to retrieve any acoustic sources could potentially be the CGC Healy. CGC Healy travels at a maximum speed of 17 knots (8.7 m/s) with a cruising speed of 12 knots (6.2 m/s) (United States Coast Guard 2013), and a maximum speed of 3 knots (1.5 m/s) when traveling through 4.5 feet (1.07 m) of sea ice (United States Coast Guard 2013). While no icebreaking cruise on the CGC Healy is scheduled during the IHA period, need may arise. Therefore, for the purposes of this IHA application, an icebreaking cruise is considered.

The R/V *Sikuliaq,* CGC Healy, or any other vessel operating a research cruise associated with the proposed action may perform the following activities during their research cruises:

- Deployment of moored and/or ice-tethered passive sensors (oceanographic measurement devices, acoustic receivers);
- Deployment of moored and/or ice-tethered active acoustic sources to transmit acoustic signals;
- Deployment of UUVs;
- Deployment of drifting buoys, with or without acoustic sources; or,
- Recovery of equipment.

Moored and Drifting Acoustic Sources

During the September 2022 cruise, active acoustic sources would be lowered from the cruise vessel while stationary, deployed on gliders and UUVs, or deployed on fixed AMOS moorings. This would be done for intermittent testing of the system components. The total amount of active source testing for ship-deployed sources used during the cruise would be 120 hours. The testing would take place near the seven source locations on Figure 1, with UUVs running tracks within the designated box. During this testing, 35 Hz, 900 Hz, and 10 kHz acoustic signals, as well as acoustic modems would be employed.

Up to seven fixed acoustic navigation sources transmitting at 900 Hz would remain in place for a year and continue transmitting during this time. These moorings would be anchored on the seabed and held in the water column with subsurface buoys. All sources would be deployed by shipboard winches, which would lower sources and receivers in a controlled manner. Anchors would be steel ''wagon wheels'' typically used for this type of deployment. Two very low frequency (VLF) sources transmitting at 35 Hz would be deployed in a similar manner. Two Ice Gateway Buoys (IGB) would also be configured with active acoustic sources. Autonomous vehicles would be able to navigate by receiving acoustic signals from multiple locations and triangulating. This is needed for vehicles that are under ice and cannot communicate with satellites. Source transmits would be offset by 15 minutes from each other (*i.e.,* sources would not be transmitting at the same time). All navigation sources would be recovered. The purpose of the navigation sources is to orient UUVs and gliders in situations when they are under ice and cannot communicate with satellites. For the purposes of this proposed action, activities potentially resulting in take would not be included in the fall 2023 cruise; a subsequent application would be provided by ONR depending on the scientific plan associated with that cruise.

TABLE 1—CHARACTERISTICS FOR THE MODELED ACOUSTIC SOURCES FOR THE PROPOSED ACTION

Platform	Acoustic source	Purpose/function	Frequency	Signal strength (dB re1uPa @1m) [1]	Band width
REMUS 600 UUV (1)	WHOI [2]/Micro-modem	Acoustic communication	900–950 Hz [3]	NTE [3] 180 dB by sys design limits.	50 Hz.
	UUV/WHOI Micro-modem	Acoustic communication	8–14 kHz [3]	NTE 185 dB by sys design limits.	5 kHz.
IGB [3] (drifting) (2)	WHOI Micro-modem	Acoustic communication	900–950 Hz	NTE 180 dB by sys design limits.	50 Hz.
	WHOI Micro-modem	Acoustic communication	8–14 kHz	NTE 185 dB by sys design limits.	5 kHz.
Mooring (9)	WHOI Micro-modem (7)	Acoustic navigation	900–950 Hz	NTE 180 dB by sys design limits.	50 Hz.

TABLE 1—CHARACTERISTICS FOR THE MODELED ACOUSTIC SOURCES FOR THE PROPOSED ACTION—Continued

Platform	Acoustic source	Purpose/function	Frequency	Signal strength (dB re1uPa @1m) [1]	Band width
	VLF [3] (2)	Acoustic navigation	35 Hz	NTE 190 dB	6 Hz.

[1] dB re 1 μPa at 1 m = decibels referenced to 1 micropascal at 1 meter.
[2] WHOI = Woods Hole Oceanographic Institution.
[3] Hz = Hertz; IGB = Ice Gateway Buoy; kHz = 1 kilohertz; NTE = not to exceed; VLF = very low frequency

Activities Not Likely To Result in Take

The following in-water activities have been determined to be unlikely to result in take of marine mammals. These activities are described here but they are not discussed further in this document.

De minimis Sources—The Navy characterizes de minimis sources as those with the following parameters: Low source levels, narrow beams, downward directed transmission, short pulse lengths, frequencies outside known marine mammal hearing ranges, or some combination of these factors (Department of the Navy, 2013b). NMFS concurs with the Navy's determination that the sources they have identified here as de minimis are unlikely to result in take of marine mammals. The following are some of the planned de minimis sources which would be used during the proposed action: Woods Hole Oceanographic Institution (WHOI) micromodem, ADCPs, ice profilers, and additional sources below 160 dB re 1 μPa used during towing operations. ADCPs may be used on moorings. Ice-profilers measure ice properties and roughness. The ADCPs and ice-profilers would all be above 200 kHz and therefore out of marine mammal hearing ranges, with the exception of the 75 kHz ADCP which has the characteristics and de minimis justification listed in Table 2. They may be employed on moorings or UUVs. Descriptions of some de minimis sources are discussed below and in Table 2. More detailed descriptions of these de minimis sources can be found in ONR's IHA application under Section 1.1.1.2.

TABLE 2—PARAMETERS FOR DE MINIMIS NON-IMPULSIVE ACTIVE SOURCES

Source name	Frequency range (kHz)	Sound pressure level (dB re 1 μPa at 1 m)	Pulse length (s)	Duty cycle (percent)	De minimis justification
ADCP	>200, 150, or 75	190	<0.001	<0.1	Very low pulse length, narrow beam, moderate source level.
Nortek Signature 500 kHz Doppler Velocity Log.	500	214	<0.1	<13	Very high frequency.
CTD [1] Attached Echosounder	5–20	160	0.004	2	Very low source level.

[1] Conductivity Temperature Depth.

Drifting Oceanographic Sensors

Observations of ocean-ice interactions require the use of sensors that are moored and embedded in the ice. For the proposed action, it will not be required to break ice to do this, as deployments can be performed in areas of low ice-coverage or free floating ice. Sensors are deployed within a few dozen meters of each other on the same ice floe. Three types of sensors would be used: autonomous ocean flux buoys, Integrated Autonomous Drifters, and ice-tethered profilers. The autonomous ocean flux buoys measure oceanographic properties just below the ocean-ice interface. The autonomous ocean flux buoys would have ADCPs and temperature chains attached, to measure temperature, salinity, and other ocean parameters in the top 20 ft (6 m) of the water column. Integrated Autonomous Drifters would have a long temperate string extending down to 656 ft (200 m) depth and would incorporate meteorological sensors, and a temperature spring to estimate ice thickness. The ice-tethered profilers would collect information on ocean temperature, salinity and velocity down to 820 ft (250 m) depth.

Up to 20 Argo-type autonomous profiling floats may be deployed in the central Beaufort Sea. Argo floats drift at 4,921 ft (1,500 m) depth, profiling from 6,562 ft (2,000 m) to the sea surface once every 10 days to collect profiles of temperature and salinity.

Moored Oceanographic Sensors

Moored sensors would capture a range of ice, ocean, and atmospheric conditions on a year-round basis. These would be bottom anchored, sub-surface moorings measuring velocity, temperature, and salinity in the upper 1,640 ft (500 m) of the water column. The moorings also collect high-resolution acoustic measurements of the ice using the ice profilers described above. Ice velocity and surface waves would be measured by 500 kHz multibeam sonars from Nortek Signatures. The moored oceanographic sensors described above use only de minimis sources and are therefore not anticipated to have the potential for impacts on marine mammals or their habitat.

On-Ice Measurements

On-ice measurement systems would be used to collect weather data. These would include an Autonomous Weather Station and an Ice Mass Balance Buoy. The Autonomous Weather Station would be deployed on a tripod; the tripod has insulated foot platforms that are frozen into the ice. The system would consist of an anemometer, humidity sensor, and pressure sensor. The Autonomous Weather Station also includes an altimeter with a sound source that is de minimis due to its very high frequency (200 kHz). The Ice Mass Balance Buoy is a 20 ft (6 m) sensor string, which is deployed through a 2 inch (5 cm) hole drilled into the ice. The string is weighted by a 2.2 lb (1 kg) lead weight, and is supported by a tripod. The buoy contains a de minimis 200 kHz altimeter and snow depth sensor. Autonomous Weather Stations and Ice Mass Balance Buoys will be deployed,

and will drift with the ice, making measurements. The instruments are destroyed as their host ice floes melt (likely in summer, roughly one year after deployment). After the instruments are deployed they cannot be recovered, and would sink to the seafloor as their host ice floes melted.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, incorporated here by reference, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Table 3 lists all species or stocks for which take is expected and proposed to be authorized for this action, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. 2020 SARs (*e.g.,* Muto *et al.* 2021), with the exception of Beaufort Sea beluga whales. The 2020 SAR for the Beaufort Sea stock of beluga whales has temporarily been withdrawn for further review, therefore, the NMFS' U.S. 2021 draft SAR represents the most recent stock assessment for this stock. All values presented in Table 3 are the most recent available at the time of publication (including from the draft 2021 SARs) online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 3—SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Monodontidae:						
Beluga Whale	*Delphinapterus leucas*	Beaufort Sea	-, -, N	39,258 (0.229, N/A, 1992)	[4] UND	104
Beluga Whale	*Delphinapterus leucas*	Eastern Chukchi Sea	-, -, N	13,305 (0.51, 8,875, 2012)	178	55
Order Carnivora—Superfamily Pinnipedia						
Family Phocidae (earless seals):						
Ringed Seal [5]	*Pusa hispida hispida*	Arctic	T, D, Y	171,418 (N/A, 158,507, 171,418.	5,100	6,459

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *www.nmfs.noaa.gov/pr/sars/.* CV is the coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable [explain if this is the case].

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[4] The 2016 guidelines for preparing SARs state that abundance estimates older than 8 years should not be used to calculate PBR due to a decline in the reliability of an aged estimate. Therefore, the PBR for this stock is considered undetermined.

[5] Abundance and associated values for ringed seals are for the U.S. population in the Bering Sea only.

As indicated above, the two species (with three managed stocks) in Table 3 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. While bowhead whales (*Balaena mysticetus*), gray whales (*Eschrichtius robustus*), bearded seals (*Erignathus barbatus*), spotted seals (*Phoca largha*), ribbon seals (*Histiophoca fasciata*), have been documented in the area, the temporal and/or spatial occurrence of these species is such that take is not expected to occur, and they are not discussed further beyond the explanation provided below.

Due to the location of the study area (*i.e.,* northern offshore, deep water), there were no calculated exposures for the bowhead whale, gray whale, spotted seal, bearded seal, and ribbon seal from quantitative modeling of acoustic sources. Bowhead and gray whales are closely associated with the shallow waters of the continental shelf in the Beaufort Sea and are unlikely to be exposed to acoustic harassment from this activity (Carretta *et al.,* 2018; Muto *et al.,* 2018). Similarly, spotted seals tend to prefer pack ice areas with water depths less than 200 m during the spring and move to coastal habitats in the summer and fall, found as far north

as 69–72° N (Muto *et al.,* 2018). Although the study area includes some waters south of 72° N, the acoustic sources with the potential to result in take of marine mammals are not found below that latitude and spotted seals are not expected to be exposed. Ribbon seals are found year-round in the Bering Sea but may seasonally range into the Chukchi Sea (Muto *et al.,* 2018). The proposed action occurs primarily in the Beaufort Sea, outside of the core range of ribbon seals, thus ribbon seals are not expected to be behaviorally harassed. Narwhals (*Monodon monoceros*) are considered extralimital in the project area and are not expected to be encountered. As no harassment is expected of the bowhead whale, gray whale, spotted seal, bearded seal, narwhal, and ribbon seal, these species will not be discussed further in this proposed notice.

The Navy has utilized Conn *et al.,* (2014) in their IHA application as an abundance estimate for ringed seals, which is based upon aerial abundance and distribution surveys conducted in the U.S. portion Bering Sea in 2012 (171,418 ringed seals; Muto *et al.,* 2021b). This value is likely an underestimate due to the lack of accounting for availability bias for seals that were in the water at the time of the surveys as well as not including seals located within the shorefast ice zone (Muto *et al.,* 2021b). Muto *et al.,* (2021b) notes that an accurate population estimate is likely larger by a factor of two or more. However, no accepted population estimate is present for Arctic ringed seals. Therefore, in the interest in making conservative decisions, NMFS will also adopt the Conn *et al.,* (2014) abundance estimate (171,418) for further analyses and discussions on this proposed action by ONR.

In addition, the polar bear (*Ursus maritimus*) and Pacific walrus (*Odobenus rosmarus*) may be found both on sea ice and/or in the water within the Beaufort Sea and Chukchi Sea. These species are managed by the U.S. Fish and Wildlife Service (USFWS) and are not considered further in this document.

Beluga Whale

Beluga whales are distributed throughout seasonally ice-covered arctic and subarctic waters of the Northern Hemisphere (Gurevich, 1980), and are closely associated with open leads and polynyas in ice-covered regions (Hazard, 1988). Belugas are both migratory and residential (non-migratory), depending on the population. Seasonal distribution is affected by ice cover, tidal conditions, access to prey, temperature, and human interaction (Frost *et al.,* 1985; Hauser *et al.,* 2014).

There are five beluga stocks recognized within U.S. waters: Cook Inlet, Bristol Bay, eastern Bering Sea, eastern Chukchi Sea, and Beaufort Sea. Two stocks, the Beaufort Sea and eastern Chukchi Sea stocks, have the potential to occur in the location of this proposed action.

A migratory Biologically Important Area (BIA) for belugas in the Eastern Chukchi and Alaskan Beaufort Sea overlaps the southern and western portion of the proposed project site. One migration corridor is in use from April to May. The second corridor, located in the Alaskan Beaufort Sea, is used by migrating belugas from September to October (Calambokidis *et al.,* 2015). During the winter, they can be found foraging in offshore waters associated with pack ice. When the sea ice melts in summer, they move to warmer river estuaries and coastal areas for molting and calving (Muto *et al.,* 2017). Annual migrations can span over thousands of kilometers. The residential Beaufort Sea populations participate in short distance movements within their range throughout the year. Based on satellite tags (Suydam *et al.,* 2001; Hauser *et al.,* 2014), there is some overlap in distribution with the eastern Chukchi Sea beluga whale stock.

During the winter, eastern Chukchi Sea belugas occur in offshore waters associated with pack ice. In the spring, they migrate to warmer coastal estuaries, bays, and rivers where they may molt (Finley, 1982; Suydam, 2009), give birth to, and care for their calves (Sergeant and Brodie, 1969). Eastern Chukchi Sea belugas move into coastal areas, including Kasegaluk Lagoon (outside of the proposed project site), in late June and animals are sighted in the area until about mid-July (Frost and Lowry, 1990; Frost *et al.,* 1993). Satellite tags attached to eastern Chukchi Sea belugas captured in Kasegaluk Lagoon during the summer showed these whales traveled 593 nm (1,100 km) north of the Alaska coastline, into the Canadian Beaufort Sea within three months (Suydam *et al.,* 2001). Satellite telemetry data from 23 whales tagged during 1998–2007 suggest variation in movement patterns for different age and/or sex classes during July-September (Suydam *et al.,* 2005). Adult males used deeper waters and remained there for the duration of the summer; all belugas that moved into the Arctic Ocean (north of 75° N) were males, and males traveled through 90 percent pack ice cover to reach deeper waters in the Beaufort Sea and Arctic Ocean (79–80° N) by late July/early August. Adult and immature female belugas remained at or near the shelf break in the south through the eastern Bering Strait into the northern Bering Sea, remaining north of Saint Lawrence Island over the winter.

Ringed Seals

Ringed seals are the most common pinniped in the proposed project site and have wide distribution in seasonally and permanently ice-covered waters of the Northern Hemisphere (North Atlantic Marine Mammal Commission, 2004). Throughout their range, ringed seals have an affinity for ice-covered waters and are well adapted to occupying both shore-fast and pack ice (Kelly, 1988c). Ringed seals can be found further offshore than other pinnipeds since they can maintain breathing holes in ice thickness greater than 6.6 ft (2 m) (Smith and Stirling, 1975). The breathing holes are maintained by ringed seals using their sharp teeth and claws found on their fore flippers. They remain in contact with ice most of the year and use it as a platform for molting in late spring to early summer, for pupping and nursing in late winter to early spring, and for resting at other times of the year (Muto *et al.,* 2018).

Ringed seals have at least two distinct types of subnivean lairs: Haulout lairs and birthing lairs (Smith and Stirling, 1975). Haul-out lairs are typically single-chambered and offer protection from predators and cold weather. Birthing lairs are larger, multi-chambered areas that are used for pupping in addition to protection from predators. Ringed seals pup on both land-fast ice as well as stable pack ice. Lentfer (1972) found that ringed seals north of Utqiaġvik, Alaska (formally known as Barrow, Alaska) build their subnivean lairs on the pack ice near pressure ridges. Since subnivean lairs were found north of Utqiaġvik, Alaska, in pack ice, they are also assumed to be found within the sea ice in the proposed project site. Ringed seals excavate subnivean lairs in drifts over their breathing holes in the ice, in which they rest, give birth, and nurse their pups for 5–9 weeks during late winter and spring (Chapskii, 1940; McLaren, 1958; Smith and Stirling, 1975). Ringed seals are born beginning in March, but the majority of births occur in early April. About a month after parturition, mating begins in late April and early May.

In Alaskan waters, during winter and early spring when sea ice is at its maximum extent, ringed seals are abundant in the northern Bering Sea, Norton and Kotzebue Sounds, and throughout the Chukchi and Beaufort

seas (Frost, 1985; Kelly, 1988c). Passive acoustic monitoring of ringed seals from a high frequency recording package deployed at a depth of 787 ft (240 m) in the Chukchi Sea 65 nautical miles (120 km) north-northwest of Utqiaġvik, Alaska detected ringed seals in the area between mid-December and late May over the 4 year study (Jones *et al.,* 2014). In addition, ringed seals have been observed near and beyond the outer boundary of the U.S. EEZ (Beland and Ireland, 2010). During the spring and early summer, ringed seals may migrate north as the ice edge recedes and spend their summers in the open water period of the northern Beaufort and Chukchi Seas (Frost, 1985). Foraging-type movements have been recorded over the continental shelf and north of the continental shelf waters (Von Duyke *et al.,* 2020). During this time, sub-adult ringed seals may also occur in the Arctic Ocean Basin (Hamilton *et al.,* 2015; Hamilton *et al.,* 2017).

With the onset of fall freeze, ringed seal movements become increasingly restricted and seals will either move west and south with the advancing ice pack with many seals dispersing throughout the Chukchi and Bering Seas, or remaining in the Beaufort Sea (Crawford *et al.,* 2012; Frost and Lowry, 1984; Harwood *et al.,* 2012). Kelly *et al.,* (2010b) tracked home ranges for ringed seals in the subnivean period (using shore-fast ice); the size of the home ranges varied from less than 1 up to 279 km^2 (median is 0.62 km^2 for adult males and 0.65 km^2 for adult females). Most (94 percent) of the home ranges were less than 3 km^2 during the subnivean period (Kelly *et al.,* 2010b). Near large polynyas, ringed seals maintain ranges, up to 7,000 km^2 during winter and 2,100 km^2 during spring (Born *et al.,* 2004). Some adult ringed seals return to the same small home ranges they occupied during the previous winter (Kelly *et al.,* 2010b). The size of winter home ranges can vary by up to a factor of 10 depending on the amount of fast ice; seal movements were more restricted during winters with extensive fast ice, and were much less restricted where fast ice did not form at high levels (Harwood *et al.,* 2015).

Of the five recognized subspecies of ringed seals, the Arctic ringed seal occurs in the Arctic Ocean and Bering Sea and is the only stock that occurs in U.S. waters. NMFS listed the Arctic ringed seal subspecies as threatened under the ESA on December 28, 2012 (77 FR 76706), primarily due to anticipated loss of sea ice through the end of the 21st century. Climate change presents a major concern for the conservation of ringed seals due to the potential for long-term habitat loss and modification (Muto *et al.,* 2021). Based upon an analysis of various life history features and the rapid changes that may occur in ringed seal habitat, ringed seals are expected to be highly sensitive to climate change (Laidre *et al.,* 2008; Kelly *et al.,* 2010a).

Critical Habitat

On January 8, 2021, NMFS published a revised proposed rule for the Designation of Critical Habitat for the Arctic Subspecies of the Ringed Seal (86 FR 1452). This proposed rule revises NMFS' December 9, 2014, proposed designation of critical habitat for the Arctic subspecies of the ringed seal under the ESA. NMFS identified the physical and biological features essential to the conservation of the species: (1) Snow-covered sea ice habitat suitable for the formation and maintenance of subnivean birth lairs used for sheltering pups during whelping and nursing, which is defined as areas of seasonal landfast (shorefast) ice and dense, stable pack ice, excluding any bottom-fast ice extending seaward from the coastline (typically in waters less than 2 m deep), that have undergone deformation and contain snowdrifts of sufficient depth, typically at least 54 cm deep; (2) Sea ice habitat suitable as a platform for basking and molting, which is defined as areas containing sea ice of 15 percent or more concentration, excluding any bottom-fast ice extending seaward from the coastline (typically in waters less than 2 m deep); and (3) Primary prey resources to support Arctic ringed seals, which are defined to be Arctic cod, saffron cod, shrimps, and amphipods. The revised proposed critical habitat designation comprises a specific area of marine habitat in the Bering, Chukchi, and Beaufort seas, extending from mean lower low water to an offshore limit within the U.S. Exclusive Economic Zone, including a portion of the ONR ARA Study Area (86 FR 1452; January 8, 2021). See the proposed ESA critical habitat rule for additional detail and a map of the proposed area.

The majority of the proposed study area was excluded from the proposed ringed seal critical habitat because the benefits of exclusion due to national security impacts outweighed the benefits of inclusion of this area (86 FR 1452; March 9, 2021). However, as stated in NMFS' second revised proposed rule for the Designation of Critical Habitat for the Arctic Subspecies of the Ringed Seal (86 FR 1452; March 9, 2021), the excluded area contains one or more of the essential features of the Arctic ringed seal's critical habitat. However, the excluded area contains features that are found throughout the specific area designated as critical habitat (87 FR 19232, April 1, 2022), therefore even though this area is excluded from critical habitat designation, habitat with the physical and biological features essential for ringed seal conservation is still available to the species. A small portion of the study area overlaps with ringed seal critical habitat as shown in Figure 2. As described later and in more detail in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section, we expect minimal impacts to marine mammal habitat as a result of the ONR's activities, including impacts on prey availability.

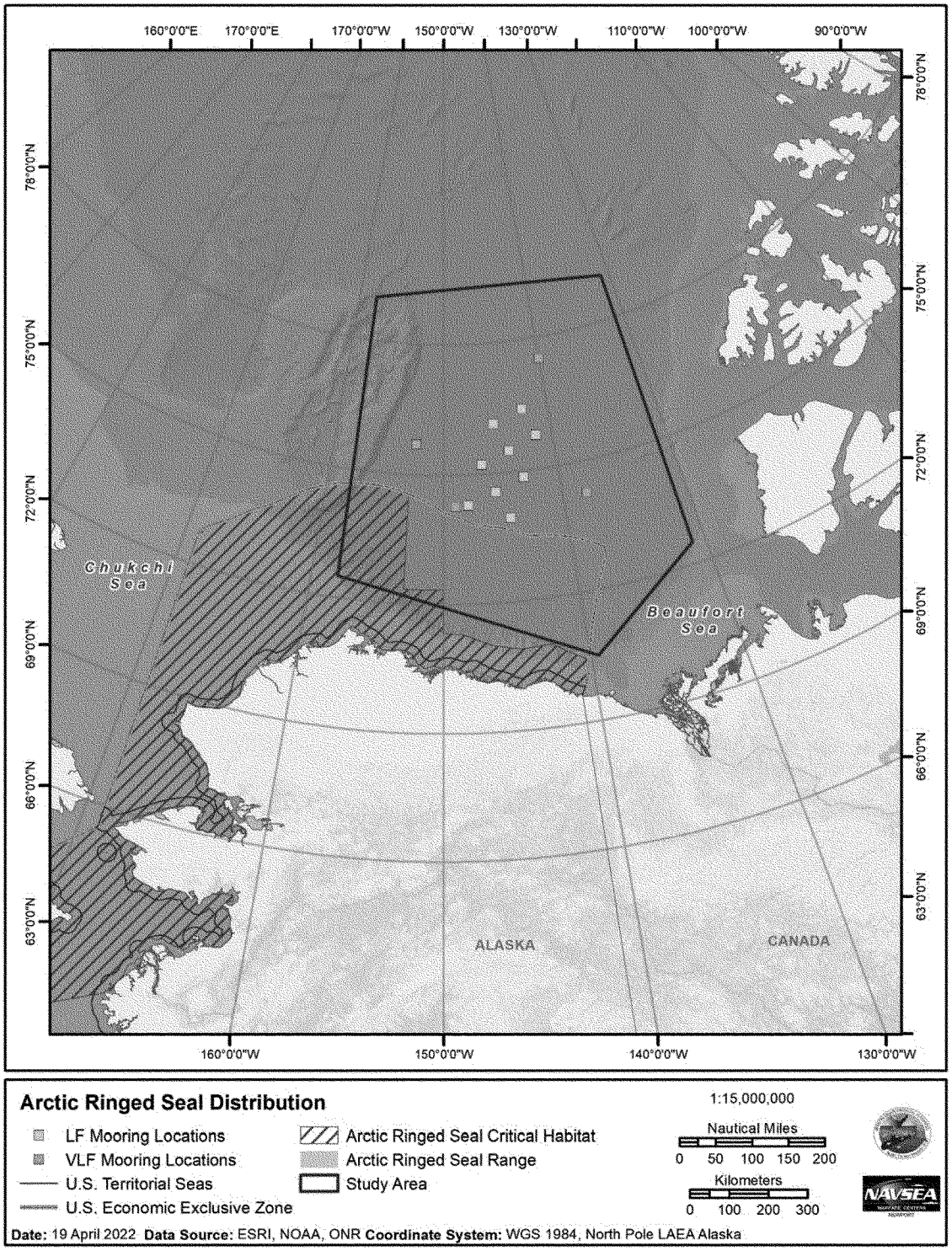

Figure 2. ONR ARA Study Area and Ringed Seal Critical Habitat Overlap

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Ice Seal Unusual Mortality Event

Since June 1, 2018, elevated strandings of ringed seals, bearded seals, spotted seals, and several unidentified seals have occurred in the Bering and Chukchi Seas. The National Oceanic and Atmospheric Administration (NOAA), as of September 2019, have declared this event an Unusual Mortality Event (UME). A UME is defined under the MMPA as a stranding that is unexpected, involves a significant die-off of any marine mammal population, and demands immediate response. From June 1, 2018 to January 7, 2022, there have been 368 dead seals reported, with 111 stranding in 2018, 164 in 2019, and 38 in 2020, and 55 in 2021, which is much greater than the average number of strandings

of about 29 seals annually. All age classes of seals have been reported stranded, and a subset of seals have been sampled for genetics and harmful algal bloom/exposure, with a few having histopathology collected. Results are pending and investigation into the cause of the UME is ongoing, yet currently unknown. No ice seals have stranded in 2022, at the time of this publication, yet the UME is still considered ongoing.

There was a previous UME involving ice seals from 2011 to 2016, which was most active in 2011–2012. A minimum of 657 seals were affected. The UME investigation determined that some of the clinical signs were due to an abnormal molt, but a definitive cause of death for the UME was never determined. The number of stranded ice seals involved in this UME, and their physical characteristics, is not at all similar to the 2011–2016 UME, as the seals in 2018–2020 have not been exhibiting hair loss or skin lesions, which were a primary finding in the 2011–2016 UME. More detailed information is available at: *https://www.fisheries.noaa.gov/alaska/marine-life-distress/2018-2022-ice-seal-unusual-mortality-event-alaska.*

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, etc.). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 4.

TABLE 4—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals may or may not impact marine mammal species or stocks.

Description of Sound Sources

Here, we first provide background information on marine mammal hearing before discussing the potential effects of the use of active acoustic sources on marine mammals.

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in Hz or cycles per second. Wavelength is the distance between two peaks of a sound wave; lower frequency sounds have longer wavelengths than higher frequency sounds and attenuate (decrease) more rapidly in shallower water. Amplitude is the height of the sound pressure wave or the 'loudness' of a sound and is typically measured using the dB scale. A dB is the ratio between a measured pressure (with sound) and a reference pressure (sound at a constant pressure, established by scientific standards). It is a logarithmic unit that accounts for large variations in amplitude; therefore, relatively small changes in dB ratings correspond to large changes in sound pressure. When referring to sound pressure levels (SPLs; the sound force per unit area), sound is referenced in the context of underwater sound pressure to one micropascal (1 μPa). One pascal is the pressure resulting from a force of one newton exerted over an area of one square meter. The source level (SL) represents the sound level at a distance of 1 m from the source (referenced to 1 μPa). The received level is the sound level at the listener's position. Note that all underwater sound levels in this document are referenced to a pressure of 1 μPa.

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. RMS is calculated by squaring all of the sound amplitudes, averaging the squares, and

then taking the square root of the average (Urick, 1983). RMS accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in all directions away from the source (similar to ripples on the surface of a pond), except in cases where the source is directional. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and far (ANSI, 1995). The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.,* vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. Because of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

Underwater sounds fall into one of two general sound types: impulsive and non-impulsive (defined in the following paragraphs). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see Southall *et al.,* (2007) for an in-depth discussion of these concepts.

Impulsive sound sources (*e.g.,* explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986; Harris, 1998; NIOSH, 1998; ISO, 2003; ANSI, 2005) and occur either as isolated events or repeated in some succession. Impulsive sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features. However and as previously noted, no impulsive acoustic sources will be used during ONR's proposed action.

Non-impulsive sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI, 1995; NIOSH, 1998). Some of these non-impulsive sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-impulsive sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar sources that intentionally direct a sound signal at a target that is reflected back in order to discern physical details about the target. These active sources are used in navigation, military training and testing, and other research activities such as the activities planned by ONR as part of the proposed action. The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Acoustic Impacts

Please refer to the information given previously regarding sound, characteristics of sound types, and metrics used in this document. Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound from active acoustic sources can potentially result in one or more of the following: temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2003; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Gotz *et al.,* 2009). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high level sounds can cause hearing loss, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. In this section, we first describe specific manifestations of acoustic effects before providing discussion specific to the proposed activities in the next section.

Permanent Threshold Shift—Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.,* 2007). Repeated sound exposure that leads to TTS could cause PTS. In severe cases of PTS, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).

Temporary Threshold Shift—TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends.

When PTS occurs, there is physical damage to the sound receptors in the ear (*i.e.,* tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.,* 2007). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent

physical injury (*e.g.,* Ward, 1997). Therefore, NMFS does not consider TTS to constitute auditory injury.

Relationships between TTS and PTS thresholds have not been studied in marine mammals—PTS data exists only for a single harbor seal (Kastak *et al.,* 2008)—but are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several decibels above (a 40-dB threshold shift approximates PTS onset; *e.g.,* Kryter *et al.,* 1966; Miller, 1974) that inducing mild TTS (a 6-dB threshold shift approximates TTS onset; *e.g.,* Southall *et al.,* 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulse sounds (such as impact pile driving pulses as received close to the source) are at least six dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level (SEL) thresholds are 15 to 20 dB higher than TTS cumulative SEL thresholds (Southall *et al.,* 2007).

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019) for summaries). For cetaceans, published data on the onset of TTS are limited to the captive bottlenose dolphin, beluga, harbor porpoise, and Yangtze finless porpoise, and for pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals, and California sea lions. These studies examine hearing thresholds measured in marine mammals before and after exposure to intense sounds. The difference between the pre-exposure and post-exposure thresholds can be used to determine the amount of threshold shift at various post-exposure times. The amount and onset of TTS depends on the exposure frequency. Sounds at low frequencies, well below the region of best sensitivity, are less hazardous than those at higher frequencies, near the region of best sensitivity (Finneran and Schlundt, 2013). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity *(i.e.,* a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.,* 2019a, 2019b, 2020a, 2020b). In addition, TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Finneran *et al.,* 2010; Kastelein *et al.,* 2014; Kastelein *et al.,* 2015a; Mooney *et al.,* 2009). This means that TTS predictions based on the total, cumulative SEL will overestimate the amount of TTS from intermittent exposures such as sonars and impulsive sources. Nachtigall *et al.* (2018) and Finneran (2018) describe the measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Another study showed that echolocating animals (including odontocetes) might have anatomical specializations that might allow for conditioned hearing reduction and filtering of low-frequency ambient noise, including increased stiffness and control of middle ear structures and placement of inner ear structures (Ketten *et al.,* 2021). Data available on noise-induced hearing loss for mysticetes are currently lacking (NMFS, 2018).

Behavioral effects—Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2003; Southall *et al.,* 2007; Weilgart, 2007; Archer *et al.,* 2010; Southall *et al.,* 2021). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). A review of marine mammal responses to anthropogenic sound was first conducted by Richardson (1995). More recent reviews (Nowacek *et al.,* 2007; Ellison *et al.,* 2012; Gomez *et al.,* 2016) addressed studies conducted since 1995 and focused on observations where the received sound level of the exposed marine mammal(s) was known or could be estimated. Gomez *et al.* (2016) conducted a review of the literature considering the contextual information of exposure in addition to received level and found that higher received levels were not always associated with more severe behavioral responses and vice versa. Southall *et al.* (2016) states that results demonstrate that some individuals of different species display clear yet varied responses, some of which have negative implications, while others appear to tolerate high levels, and that responses may not be fully predictable with simple acoustic exposure metrics (*e.g.,* received sound level). Rather, the authors state that differences among species and individuals along with contextual aspects of exposure (*e.g.,* behavioral state) appear to affect response probability.

The following subsections provide examples of behavioral responses that provide an idea of the variability in behavioral responses that would be expected given the differential sensitivities of marine mammal species to sound and the wide range of potential acoustic sources to which a marine mammal may be exposed. Behavioral responses that could occur for a given sound exposure should be determined from the literature that is available for each species, or extrapolated from closely related species when no information exists, along with contextual factors. Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance

might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, the stock, or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2003). There are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely, and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Costa *et al.,* 2003; Ng and Leung, 2003; Nowacek *et al.,* 2004; Goldbogen *et al.,* 2013). Seals exposed to non-impulsive sources with a received sound pressure level within the range of calculated exposures (142–193 dB re 1 μPa), have been shown to change their behavior by modifying diving activity and avoidance of the sound source (Götz *et al.,* 2010; Kvadsheim *et al.,* 2010). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.;* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007; Melcón *et al.,* 2012). In addition, behavioral state of the animal plays a role in the type and severity of a behavioral response, such as disruption to foraging (*e.g.,* Silve *et al.,* 2016; Wensveen *et al.,* 2017). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal. Goldbogen *et al.* (2013) indicate that disruption of feeding and displacement could impact individual fitness and health. However, for this to be true, we would have to assume that an individual could not compensate for this lost feeding opportunity by either immediately feeding at another location, by feeding shortly after cessation of acoustic exposure, or by feeding at a later time. There is no indication this is the case, particularly since unconsumed prey would likely still be available in the environment in most cases following the cessation of acoustic exposure. Information on or estimates of the energetic requirements of the individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal will help better inform a determination of whether foraging disruptions incur fitness consequences.

Respiration naturally varies with different behaviors, and variations in respiration rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Studies with captive harbor porpoises showed increased respiration rates upon introduction of acoustic alarms (Kastelein *et al.,* 2001; Kastelein *et al.,* 2006) and emissions for underwater data transmission (Kastelein *et al.,* 2005). Various studies also have shown that species and signal characteristics are important factors in whether respiration rates are unaffected or change, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (*e.g.,* Kastelein *et al.,* 2005, 2006, 2018; Gailey *et al.,* 2007; Isojunno *et al.,* 2018).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003; Foote *et al.,* 2004), while right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007; Rolland *et al.,* 2012). Killer whales off the northwestern coast of the United States have been observed to increase the duration of primary calls once a threshold in observing vessel density (*e.g.,* whale watching) was reached, which has been suggested as a response to increased masking noise produced by the vessels (Foote *et al.,* 2004; NOAA, 2014). In some cases, however, animals may cease or alter sound production in response to underwater sound (*e.g.,* Bowles *et al.,* 1994; Castellote *et al.,* 2012; Cerchio *et al.,* 2014). Studies also demonstrate that even low levels of noise received far from the noise source can induce changes in vocalization and/or behavioral responses (Blackwell *et al.,* 2013, 2015).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). Avoidance is qualitatively different from the flight response, but also differs in the magnitude of the response (*i.e.,* directed movement, rate of travel, *etc.*). Oftentimes avoidance is temporary, and animals return to the area once the noise has ceased. Acute avoidance responses have been observed in captive porpoises and pinnipeds exposed to a number of different sound sources (Kastelein *et al.,* 2001; Finneran *et al.,* 2003; Kastelein *et al.,* 2006a; Kastelein *et al.,* 2006b; Kastelein *et al.,* 2015b; Kastelein *et al.,* 2015c; Kastelein *et al.,* 2018). Short-term avoidance of seismic surveys, low frequency emissions, and acoustic deterrents have also been noted in wild populations of odontocetes (Bowles *et al.,* 1994; Goold, 1996; Goold and Fish, 1998; Stone *et al.,* 2000; Morton and Symonds, 2002; Hiley *et al.,* 2021) and to some extent in mysticetes (Malme *et al.,* 1984; McCauley *et al.,* 2000; Gailey *et al.,* 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Blackwell *et al.,* 2004; Bejder *et al.,* 2006; Teilmann *et al.,* 2006).

Forney *et al.* (2017) described the potential effects of noise on marine mammal populations with high site

fidelity, including displacement and auditory masking. In cases of Western gray whales (Weller *et al.,* 2006) and beaked whales, anthropogenic effects in areas where they are resident or exhibit site fidelity could cause severe biological consequences, in part because displacement may adversely affect foraging rates, reproduction, or health, while an overriding instinct to remain in the area could lead to more severe acute effects. Avoidance of overlap between disturbing noise and areas and/or times of particular importance for sensitive species may be critical to avoiding population-level impacts because (particularly for animals with high site fidelity) there may be a strong motivation to remain in the area despite negative impacts.

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (Evans and England, 2001). There are limited data on flight response for marine mammals in water; however, there are examples of this response in species on land. For instance, the probability of flight responses in Dall's sheep *Ovis dalli dalli* (Frid, 2003), hauled-out ringed seals *Phoca hispida* (Born *et al.,* 1999), Pacific brant (*Branta bernicl nigricans*), and Canada geese (*B. canadensis*) increased as a helicopter or fixed-wing aircraft more directly approached groups of these animals (Ward *et al.,* 1999). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder *et al.,* 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. As noted, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; NRC, 2003; Wartzok *et al.,* 2003). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.,* 1997; Finneran *et al.,* 2003). Observed responses of wild marine mammals to loud impulsive sound sources (typically seismic airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; see also Richardson *et al.,* 1995; Nowacek *et al.,* 2007).

Data on hooded seals (*Cystophora cristata*) indicate avoidance responses to signals above 160–170 dB re 1 μPa (Kvadsheim *et al.,* 2010), and data on grey (*Halichoerus grypus*) and harbor seals indicate avoidance response at received levels of 135–144 dB re 1 μPa (Götz *et al.,* 2010). In each instance where food was available, which provided the seals motivation to remain near the source, habituation to the signals occurred rapidly. In the same study, it was noted that habituation was not apparent in wild seals where no food source was available (Götz *et al.,* 2010). This implies that the motivation of the animal is necessary to consider in determining the potential for a reaction. In one study to investigate the under-ice movements and sensory cues associated with under-ice navigation of ice seals, acoustic transmitters (60–69 kHz at 159 dB re 1 μPa at 1 m) were attached to ringed seals (Wartzok *et al.,* 1992a, Wartzok *et al.,* 1992b). An acoustic tracking system then was installed in the ice to receive the acoustic signals and provide real-time tracking of ice seal movements. Although the frequencies used in this study are at the upper limit of ringed seal hearing, the ringed seals appeared unaffected by the acoustic transmissions, as they were able to maintain normal behaviors (*e.g.,* finding breathing holes).

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.,* when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been observed in marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates and efficiency (*e.g.,* Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both *(e.g.,* Harrington and Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998).

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multi-day substantive behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Behavioral response studies have been conducted on odontocete responses to sonar. Sperm whales were exposed to pulsed active sonar (1–2 kHz) at moderate source levels and high source levels, as well as continuously active sonar at moderate levels for which the summed energy (SEL) equaled the summed energy of the high source level pulsed sonar (Isojunno *et al.,* 2020). Foraging behavior did not change during exposures to moderate source level sonar, but non-foraging behavior increased during exposures to high source level sonar and to the continuous sonar, indicating that the energy of the sound (the SEL) was a better predictor of response than SPL. Time of day of the exposure was also an important covariate in determining the amount of non-foraging behavior, as were order effects (*e.g.* the SEL of the previous exposure); Isojunno *et al.* (2021) found that higher SELs reduced sperm whale buzzing (*i.e.,* foraging).

Duration of continuous sonar activity also appears to impact sperm whale displacement and foraging activity (Stanistreet *et al.,* 2022). During long bouts of sonar lasting up to 13 consecutive hours, occurring repeatedly over an 8 day naval exercise (median and maximum SPL = 120 dB and 164 dB), sperm whales substantially reduced how often they produced clicks during sonar, indicating a decrease or cessation in foraging behavior. Curé *et al.* (2021) also found that sperm whales exposed to continuous and pulsed active sonar were more likely to produce low or medium severity responses with higher cumulative SEL. Specifically, the probability of observing a low severity response increased to 0.5 at approximately 173 dB SEL and observing a medium severity response reached a probability of 0.35 at cumulative SELs between 179 and 189 dB. These results again demonstrate that the behavioral state and environment of the animal mediates the likelihood of a behavioral response, as do the characteristics (*e.g.,* frequency, energy level) of the sound source itself.

Many of the contextual factors resulting from the behavioral response studies (*e.g.,* close approaches by multiple vessels or tagging) would not occur during the proposed action. Odontocete behavioral responses to acoustic transmissions from non-impulsive sources used during the proposed action would likely be a result of the animal's behavioral state and prior experience rather than external variables such as ship proximity; thus, any behavioral responses are expected to be minimal and short term.

To assess the strength of behavioral changes and responses to external sounds and SPLs associated with changes in behavior, Southall *et al.,* (2007) developed and utilized a severity scale, which is a 10 point scale ranging from no effect (labeled 0), effects not likely to influence vital rates (low; labeled from 1 to 3), effects that could affect vital rates (moderate; labeled 4 to 6), to effects that were thought likely to influence vital rates (high; labeled 7 to 9). Southall *et al.,* (2021) updated the severity scale by integrating behavioral context (*i.e.,* survival, reproduction, and foraging) into severity assessment. For non-impulsive sounds (*i.e.,* similar to the sources used during the proposed action), data suggest that exposures of pinnipeds to sources between 90 and 140 dB re 1 μPa do not elicit strong behavioral responses; no data were available for exposures at higher received levels for Southall *et al.,* (2007) to include in the severity scale analysis. Reactions of harbor seals were the only available data for which the responses could be ranked on the severity scale. For reactions that were recorded, the majority (17 of 18 individuals/groups) were ranked on the severity scale as a 4 (defined as moderate change in movement, brief shift in group distribution, or moderate change in vocal behavior) or lower; the remaining response was ranked as a 6 (defined as minor or moderate avoidance of the sound source).

Behavioral Responses to Ice Breaking Noise- Ringed seals on pack ice showed various behaviors when approached by an icebreaking vessel. A majority of seals dove underwater when the ship was within 0.5 nm (0.93 km) while others remained on the ice. However, as icebreaking vessels came closer to the seals, most dove underwater. Ringed seals have also been observed foraging in the wake of an icebreaking vessel (Richardson *et al.,* 1995). In studies by Alliston (1980; 1981), there was no observed change in the density of ringed seals in areas that had been subject to icebreaking. Alternatively, ringed seals may have preferentially established breathing holes in the ship tracks after the icebreaker moved through the area. Previous observations and studies using icebreaking ships provide a greater understanding in how seal behavior may be affected by a vessel transiting through the area.

Adult ringed seals spend up to 20 percent of the time in subnivean lairs during the winter season (Kelly *et al.,* 2010b). Ringed seal pups spend about 50 percent of their time in the lair during the nursing period (Lydersen and Hammill, 1993). During the warm season ringed seals haul out on the ice. In a study of ringed seal haul out activity by Born *et al.,* (2002), ringed seals spent 25–57 percent of their time hauled out in June, which is during their molting season. Ringed seal lairs are typically used by individual seals (haulout lairs) or by a mother with a pup (birthing lairs); large lairs used by many seals for hauling out are rare (Smith and Stirling, 1975). If the non-impulsive acoustic transmissions are heard and are perceived as a threat, ringed seals within subnivean lairs could react to the sound in a similar fashion to their reaction to other threats, such as polar bears (their primary predators), although the type of sound would be novel to them. Responses of ringed seals to a variety of human-induced sounds (*e.g.,* helicopter noise, snowmobiles, dogs, people, and seismic activity) have been variable; some seals entered the water and some seals remained in the lair. However, in all instances in which observed seals departed lairs in response to noise disturbance, they subsequently reoccupied the lair (Kelly *et al.,* 1988d).

Ringed seal mothers have a strong bond with their pups and may physically move their pups from the birth lair to an alternate lair to avoid predation, sometimes risking their lives to defend their pups from potential predators (Smith, 1987). If a ringed seal mother perceives the proposed acoustic sources as a threat, the network of multiple birth and haulout lairs allows the mother and pup to move to a new lair (Smith and Hammill, 1981; Smith and Stirling, 1975). The acoustic sources from this proposed action are not likely to impede a ringed seal from finding a breathing hole or lair, as captive seals have been found to primarily use vision to locate breathing holes and no effect to ringed seal vision would occur from the acoustic disturbance (Elsner *et al.,* 1989; Wartzok *et al.,* 1992a). It is anticipated that a ringed seal would be able to relocate to a different breathing hole relatively easily without impacting their normal behavior patterns.

Stress responses— An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious

fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003).

Auditory masking— Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions.

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is anthropogenic, it may be considered harassment when disrupting or significantly altering behavior patterns. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013).

Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking. Due to the transient nature of marine mammals to move and avoid disturbance, masking is not likely to have long-term impacts on marine mammal species within the proposed study area.

Potential Effects on Prey— The marine mammal species in the study area feed on marine invertebrates and fish. Studies of sound energy effects on invertebrates are few, and primarily identify behavioral responses. It is expected that most marine invertebrates would not sense the frequencies of the acoustic transmissions from the acoustic sources associated with the proposed action. Although acoustic sources used during the proposed action may briefly impact individuals, intermittent exposures to non-impulsive acoustic sources are not expected to impact survival, growth, recruitment, or reproduction of widespread marine invertebrate populations.

The fish species residing in the study area include those that are closely associated with the deep ocean habitat of the Beaufort Sea. Nearly 250 marine fish species have been described in the Arctic, excluding the larger parts of the sub-Arctic Bering, Barents, and Norwegian Seas (Mecklenburg *et al.,* 2011). However, only about 30 are known to occur in the Arctic waters of the Beaufort Sea (Christiansen and Reist, 2013). Although hearing capability data only exist for fewer than 100 of the 32,000 named fish species, current data suggest that most species of fish detect sounds from 50 to 100 Hz, with few fish hearing sounds above 4 kHz (Popper, 2008). It is believed that most fish have the best hearing sensitivity from 100 to 400 Hz (Popper, 2003). Fish species in the study area are expected to hear the low-frequency sources associated with the proposed action, but most are not expected to detect sound from the mid-frequency sources. Human generated sound could alter the behavior of a fish in a manner than would affect its way of living, such as where it tries to locate food or how well it could find a mate. Behavioral responses to loud noise could include a startle response, such as the fish swimming away from the source, the fish ''freezing'' and staying in place, or scattering (Popper, 2003). Misund (1997) found that fish ahead of a ship showed avoidance reactions at ranges of 160 to 489 ft (49 to 149 m). Avoidance behavior of vessels, vertically or horizontally in the water column, has been reported for cod and herring, and was attributed to vessel noise. While acoustic sources associated with the proposed action may influence the behavior of some fish species, other fish species may be equally unresponsive. Overall effects to fish from the proposed

action would be localized, temporary, and infrequent.

Effects to Physical and Foraging Habitat—Ringed seals haul out on pack ice during the spring and summer to molt (Reeves *et al.,* 2002; Born *et al.,* 2002). Additionally, some studies (Alliston, 1980; 1981) suggested that ringed seals might preferentially establish breathing holes in ship tracks after vessels move through the area. The amount of ice habitat disturbed by activities is small relative to the amount of overall habitat available and there will be no permanent or longer-term loss or modification of physical ice habitat used by ringed seals. Vessel movement would have minimal effect on physical beluga habitat as beluga habitat is solely within the water column. Furthermore, the deployed sources that would remain in use after the vessels have left the survey area have low duty cycles and lower source levels, and any impacts to the acoustic habitat of marine mammals would be minimal.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. For this military readiness activity, the MMPA defines ''harassment'' as (i) Any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) Any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where the behavioral patterns are abandoned or significantly altered (Level B harassment).

Authorized takes would be by Level B harassment only, in the form of disruption of behavioral patterns and/or TTS for individual marine mammals resulting from exposure to ONR's acoustic sources. Based on the nature of the activity, Level A harassment is neither anticipated nor proposed to be authorized.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). For the proposed IHA, ONR employed an advanced model known as the Navy Acoustic Effects Model (NAEMO) for assessing the impacts of underwater sound. Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μPa)) for continuous (*e.g.,* vibratory pile-driving, drilling) and above RMS SPL 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources.

In this case, NMFS is proposing to adopt the Navy's approach to estimating incidental take by Level B harassment from the active acoustic sources for this action, which includes use of dose response functions. The Navy's dose response functions were developed to estimate take from sonar and similar transducers, but are not applicable to ice breaking. Multi-year research efforts have conducted sonar exposure studies for odontocetes and mysticetes (Miller *et al.,* 2012; Sivle *et al.,* 2012). Several studies with captive animals have provided data under controlled circumstances for odontocetes and pinnipeds (Houser *et al.,* 2013a; Houser *et al.,* 2013b). Moretti *et al.,* (2014) published a beaked whale dose-response curve based on passive acoustic monitoring of beaked whales during U.S. Navy training activity at Atlantic Underwater Test and Evaluation Center during actual Anti-Submarine Warfare exercises. This information necessitated the update of the behavioral response criteria for the U.S. Navy's environmental analyses.

Southall *et al.,* (2007), and more recently Southall *et al.,* (2019), synthesized data from many past behavioral studies and observations to determine the likelihood of behavioral reactions at specific sound levels. While in general, the louder the sound source the more intense the behavioral response, it was clear that the proximity of a sound source and the animal's experience, motivation, and conditioning were also critical factors influencing the response (Southall *et al.,* 2007; Southall *et al.,* 2019). After examining all of the available data, the authors felt that the derivation of thresholds for behavioral response based solely on exposure level was not supported because context of the animal at the time of sound exposure was an important factor in estimating response. Nonetheless, in some conditions, consistent avoidance reactions were noted at higher sound levels depending on the marine mammal species or group allowing conclusions to be drawn. Phocid seals showed avoidance reactions at or below 190 dB re 1 μPa at 1m; thus, seals may actually receive levels adequate to produce TTS before avoiding the source.

Odontocete behavioral criteria for non-impulsive sources were updated based on controlled exposure studies for dolphins and sea mammals, sonar, and safety (3S) studies where odontocete behavioral responses were reported after

exposure to sonar (Antunes *et al.,* 2014; Houser *et al.,* 2013b; Miller *et al.,* 2011; Miller *et al.,* 2014; Miller *et al.,* 2012). For the 3S study, the sonar outputs included 1–2 kHz up- and down-sweeps and 6–7 kHz up-sweeps; source levels were ramped up from 152–158 dB re 1 μPa to a maximum of 198–214 re 1 μPa at 1 m. Sonar signals were ramped up over several pings while the vessel approached the mammals. The study did include some control passes of ships with the sonar off to discern the behavioral responses of the mammals to vessel presence alone versus active sonar.

The controlled exposure studies included exposing the Navy's trained bottlenose dolphins to mid-frequency sonar while they were in a pen. Mid-frequency sonar was played at 6 different exposure levels from 125–185 dB re 1 μPa (rms). The behavioral response function for odontocetes resulting from the studies described above has a 50 percent probability of response at 157 dB re 1 μPa. Additionally, distance cutoffs (20 km for MF cetaceans) were applied to exclude exposures beyond which the potential of significant behavioral responses is considered to be unlikely.

The pinniped behavioral threshold was updated based on controlled exposure experiments on the following captive animals: hooded seal, gray seal (*Halichoerus grypus*), and California sea lion (Götz *et al.,* 2010; Houser *et al.,* 2013a; Kvadsheim *et al.,* 2010). Hooded seals were exposed to increasing levels of sonar until an avoidance response was observed, while the grey seals were exposed first to a single received level multiple times, then an increasing received level. Each individual California sea lion was exposed to the same received level ten times. These exposure sessions were combined into a single response value, with an overall response assumed if an animal responded in any single session. The resulting behavioral response function for pinnipeds has a 50 percent probability of response at 166 dB re 1 μPa. Additionally, distance cutoffs (10 km for pinnipeds) were applied to exclude exposures beyond which the potential of significant behavioral responses is considered unlikely. For additional information regarding marine mammal thresholds for PTS and TTS onset, please see NMFS (2018) and Table 6.

Empirical evidence has not shown responses to non-impulsive acoustic sources that would constitute take beyond a few km from a non-impulsive acoustic source, which is why NMFS and the Navy conservatively set distance cutoffs for pinnipeds and mid-frequency cetaceans (U.S. Department of the Navy, 2017a). The cutoff distances for fixed sources are different from those for moving sources, as they are treated as individual sources in Navy modeling given that the distance between them is significantly greater than the range to which environmental effects can occur. Fixed source cutoff distances used were 2.7 nm (5 km) for pinnipeds and 5.4 nm (10 km) for beluga whales (Table 5). As some of the on-site drifting sources could come closer together, the drifting source cutoffs applied were 5.4 nm (10 km) for pinnipeds and 10.8 nm (20 km) for beluga whales (Table 5). Regardless of the received level at that distance, take is not estimated to occur beyond these cutoff distances. Range to thresholds were calculated for the noise associated with icebreaking in the study area. These all fall within the same cutoff distances as non-impulsive acoustic sources; range to behavioral threshold for both beluga whales and ringed seal were under 2.7 nm (5 km), and range to TTS threshold for both under 15 m (Table 5).

TABLE 5—THRESHOLDS[1] AND CUTOFF DISTANCES FOR SOURCES BY SPECIES

Species	Behavioral threshold for non-impulsive acoustic sources	Fixed source behavioral threshold cutoff distance[3] (km)	Drifting source behavioral threshold cutoff distance[3] (km)	Behavioral threshold for ice breaking sources	Ice breaking source cutoff distance[3] (km)	TTS threshold	PTS threshold
Ringed Seal ..	Pinniped Dose Response Function[2].	5	10	120 dB re 1 μPa step function.	<5	181 dB SEL cumulative.	201 dB SEL cumulative.
Beluga Whale	Mid-Frequency BRF dose Response Function[2].	10	20	120 dB re 1 μPa step function.	<15	178 dB SEL cumulative.	198 dB SEL cumulative.

[1] The threshold values provided are assumed for when the source is within the animal's best hearing sensitivity. The exact threshold varies based on the overlap of the source and the frequency weighting.
[2] See Figure 6–1 in application.
[3] Take is not estimated to occur beyond these cutoff distances, regardless of the received level.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). ONR's proposed activity includes the use of non-impulsive acoustic sources; however, Level A harassment is not expected as a result of the proposed activities nor is it proposed to be authorized by NMFS.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 6—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{p,0\text{-pk,flat}}$: 219 dB; $L_{E,p,\ LF,24h}$: 183 dB	*Cell 2:* $L_{E,p,\ LF,24h}$: 199 dB
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{p,0\text{-pk,flat}}$: 230 dB; $L_{E,p,\ MF,24h}$: 185 dB	*Cell 4:* $L_{E,p,\ MF,24h}$: 198 dB
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{p,0\text{-pk,flat}}$: 202 dB; $L_{E,p,\ HF,24h}$: 155 dB	*Cell 6:* $L_{E,p,\ HF,24h}$: 173 dB

TABLE 6—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT—Continued

Hearing group	PTS onset thresholds * (received level)	
	Impulsive	Non-impulsive
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{p,0\text{-pk,flat}}$: 218 dB; $L_{E,p,\ PW,24h}$: 185 dB	*Cell 8:* $L_{E,p,\ PW,24h}$: 201 dB
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{p,0\text{-pk,flat}}$: 232 dB; $L_{E,p,\ OW,24h}$: 203 dB	*Cell 10:* $L_{E,p,\ OW,24h}$: 219 dB

* Dual metric thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds are recommended for consideration.

Note: Peak sound pressure level ($L_{p,0\text{-pk}}$) has a reference value of 1 μPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1μPa^{2}s. In this Table, thresholds are abbreviated to be more reflective of International Organization for Standardization standards (ISO 2017). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals (*i.e.,* 7 Hz to 160 kHz). The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these thresholds will be exceeded.

Quantitative Modeling

The Navy performed a quantitative analysis to estimate the number of marine mammals likely to be exposed to underwater acoustic transmissions above the previously described threshold criteria during the proposed action. Inputs to the quantitative analysis included marine mammal density estimates obtained from the Kaschner *et al.* (2006) habitat suitability model and Cañadas *et al.* (2020), marine mammal depth occurrence (U.S. Department of the Navy, 2017b), oceanographic and mammal hearing data, and criteria and thresholds for levels of potential effects. The quantitative analysis consists of computer modeled estimates and a post-model analysis to determine the number of potential animal exposures. The model calculates sound energy propagation from the proposed non-impulsive acoustic sources, the sound received by animat (virtual animal) dosimeters representing marine mammals distributed in the area around the modeled activity, and whether the sound received by animats exceeds the thresholds for effects.

The Navy developed a set of software tools and compiled data for estimating acoustic effects on marine mammals without consideration of behavioral avoidance or mitigation. These tools and data sets serve as integral components of the Navy Acoustic Effects Model (NAEMO). In NAEMO, animats are distributed non-uniformly based on species-specific density, depth distribution, and group size information and animats record energy received at their location in the water column. A fully three-dimensional environment is used for calculating sound propagation and animat exposure in NAEMO. Site-specific bathymetry, sound speed profiles, wind speed, and bottom properties are incorporated into the propagation modeling process. NAEMO calculates the likely propagation for various levels of energy (sound or pressure) resulting from each source used during the training event.

NAEMO then records the energy received by each animat within the energy footprint of the event and calculates the number of animats having received levels of energy exposures that fall within defined impact thresholds. Predicted effects on the animats within a scenario are then tallied and the highest order effect (based on severity of criteria; *e.g.,* PTS over TTS) predicted for a given animat is assumed. Each scenario, or each 24-hour period for scenarios lasting greater than 24 hours is independent of all others, and therefore, the same individual marine mammal (as represented by an animat in the model environment) could be impacted during each independent scenario or 24-hour period. In few instances, although the activities themselves all occur within the proposed study location, sound may propagate beyond the boundary of the study area. Any exposures occurring outside the boundary of the study area are counted as if they occurred within the study area boundary. NAEMO provides the initial estimated impacts on marine species with a static horizontal distribution (*i.e.,* animats in the model environment do not move horizontally).

There are limitations to the data used in the acoustic effects model, and the results must be interpreted within this context. While the best available data and appropriate input assumptions have been used in the modeling, when there is a lack of definitive data to support an aspect of the modeling, conservative modeling assumptions have been chosen (*i.e.,* assumptions that may result in an overestimate of acoustic exposures):

- Animats are modeled as being underwater, stationary, and facing the source and therefore always predicted to receive the maximum potential sound level at a given location (*i.e.,* no porpoising or pinnipeds' heads above water);
- Animats do not move horizontally (but change their position vertically within the water column), which may overestimate physiological effects such as hearing loss, especially for slow moving or stationary sound sources in the model;
- Animats are stationary horizontally and therefore do not avoid the sound source, unlike in the wild where animals would most often avoid exposures at higher sound levels, especially those exposures that may result in PTS;
- Multiple exposures within any 24-hour period are considered one continuous exposure for the purposes of calculating potential threshold shift, because there are not sufficient data to estimate a hearing recovery function for the time between exposures; and
- Mitigation measures were not considered in the model. In reality, sound-producing activities would be reduced, stopped, or delayed if marine mammals are detected by visual monitoring.

Due to these inherent model limitations and simplifications, model-estimated results should be further analyzed, considering such factors as the range to specific effects, avoidance, and the likelihood of successfully implementing mitigation measures. This analysis uses a number of factors in addition to the acoustic model results to predict acoustic effects on marine mammals, as described below in the

Marine Mammal Occurrence and Take Estimation section.

The underwater radiated noise signature for icebreaking in the central Arctic Ocean by CGC Healy during different types of ice-cover was characterized in Roth *et al.* (2013). The radiated noise signatures were characterized for various fractions of ice cover. For modeling, the 8/10 and 3/10 ice cover were used. Each modeled day of icebreaking consisted of 16 hours of 8/10 ice cover and 8 hours of 3/10 ice cover. The sound signature of the 5/10 icebreaking activities, which would correspond to half-power icebreaking, was not reported in (Roth *et al.* 2013); therefore, the full-power signature was used as a conservative proxy for the half-power signature. Icebreaking was modeled for eight days total. Since ice forecasting cannot be predicted more than a few weeks in advance, it is unknown if icebreaking would be needed to deploy or retrieve the sources after one year of transmitting. Therefore, the potential for an icebreaking cruise on CGC Healy was conservatively analyzed within this request for an IHA. As the R/V *Sikuliaq* is not expected to be ice breaking, acoustic noise created by ice breaking is only modeled for the CGC Healy. Figures 5a and 5b in Roth *et al.* (2013) depict the source spectrum level versus frequency for 8/10 and 3/10 ice cover, respectively. The sound signature of each of the ice coverage levels was broken into 1-octave bins (Table 7). In the model, each bin was included as a separate source on the modeled vessel. When these independent sources go active concurrently, they simulate the sound signature of CGC Healy. The modeled source level summed across these bins was 196.2 dB for the 8/10 signature and 189.3 dB for the 3/10 ice signature. These source levels are a good approximation of the icebreaker's observed source level (provided in Figure 4b of (Roth *et al.,* 2013)). Each frequency and source level was modeled as an independent source, and applied simultaneously to all of the animats within NAEMO. Each second was summed across frequency to estimate sound pressure level (root mean square [SPL_{RMS}]). Any animat exposed to sound levels greater than 120 dB was considered a take by Level B harassment. For PTS and TTS, determinations, sound exposure levels were summed over the duration of the test and the transit to the deep water deployment area. The method of quantitative modeling for icebreaking is considered to be a conservative approach; therefore, the number of takes estimated for icebreaking are likely an overestimate and would not be expected to reach that level.

TABLE 7—MODELED BINS FOR 8/10 (FULL POWER) AND 3/10 (QUARTER POWER) ICE COVERAGE ICE BREAKING ON THE CGC HEALY

Frequency (Hz)	8/10 source level (dB)	3/10 source level (dB)
25	189	187
50	188	182
100	189	179
200	190	177
400	188	175
800	183	170
1600	177	166
3200	176	171
6400	172	168
12800	167	164

For non-impulsive sources, NAEMO calculates the SPL and SEL for each active emission during an event. This is done by taking the following factors into account over the propagation paths: bathymetric relief and bottom types, sound speed, and attenuation contributors such as absorption, bottom loss, and surface loss. Platforms such as a ship using one or more sound sources are modeled in accordance with relevant vehicle dynamics and time durations by moving them across an area whose size is representative of the testing event's operational area.

Marine Mammal Occurrence and Take Estimation

In this section we provide information about the occurrence of marine mammals, including density or other relevant information that will inform the take calculations. We also describe how the marine mammal occurrence information is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization.

The beluga whale density numbers utilized for quantitative acoustic modeling are from the Navy Marine Species Density Database (U.S. Department of the Navy 2014). Where available (*i.e.,* June through 15 October over the continental shelf primarily), density estimates used were from Duke density modeling based upon line-transect surveys (Cañadas *et al.,* 2020). The remaining seasons and geographic area were based on the habitat-based modeling by Kaschner *et al.* (2006) and Kaschner (2004). Density for beluga whales was not distinguished by stock and varied throughout the project area geographically and monthly; the range of densities in the project area during September I shown in Table 8. The density estimates for ringed seals are based on the habitat suitability modeling by Kaschner *et al.,* (2006) and Kaschner (2004) and shown in Table 8 as well.

TABLE 8—DENSITY ESTIMATES OF IMPACTED SPECIES

Common name	Density estimates (animals/km^2)
Beluga whale (Beaufort Sea) Stock	0.000506 to 0.5176
Beluga whale (Eastern Chukchi Sea Stock).	
Ringed seal (Arctic Stock)	0.1108 to 0.3562

Take of all species would occur by Level B harassment only. NAEMO estimated for potential TTS exposure and predicted one exposure of ringed seals may occur as a result of the proposed activities. Table 9 shows the total number of requested takes by Level B harassment that NMFS proposes to authorize for both beluga whale stocks and the Arctic ringed seal stock based upon NAEMO modeled results.

Density estimates for beluga whales are equal as estimates were not distinguished by stock (Kaschner *et al.,* 2006; Kaschner, 2004). The ranges of the Beaufort Sea and Eastern Chukchi Sea beluga whales vary within the study area throughout the year (Hauser *et al.,* 2014). Based upon the limited information available regarding the expected spatial distributions of each stock within the study area, take has been apportioned equally to each stock (Table 9). In addition, in NAEMO, animats do not move horizontally or react in any way to avoid sound. Therefore, the current model may overestimate non-impulsive acoustic impacts.

TABLE 9—REQUESTED TAKE BY LEVEL B HARASSMENT

Species	Non-impulsive active acoustics (behavioral)	Icebreaking (behavioral)	Icebreaking (TTS)	Total proposed authorized take	Percentage of stock requested for take [1]
				Behavioral/TTS	
Beluga whale—Beaufort Sea Stock	134	11	0	145/0	0.369
Beluga whale—Eastern Chukchi Sea Stock	134	11	0	145/0	1.09
Ringed seal	2,839	538	1	3,377/1	1.97

[1] Percentage of stock taken calculated based on proportion of number of Level B takes per the stock population estimate provided in Table 3–1 in the application.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)). The NDAA for FY 2004 amended the MMPA as it relates to military readiness activities and the incidental take authorization process such that ''least practicable impact'' shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation for Marine Mammals and Their Habitat

The Navy would be required to abide by the mitigation measures below. These measures are expected to: further minimize the likelihood of ship strikes; reduce the likelihood that marine mammals are exposed to sound levels during acoustic source deployment that would be expected to result in TTS or more severe behavioral responses and also to ensure that there are no other interactions between the deployed gear and marine mammals, and; further ensure that there are no impacts to subsistence uses.

Ships operated by or for the Navy have at least one personnel assigned to stand watch at all times, day and night, when moving through the water. Watch personnel must be trained through the U.S. Navy Marine Species Awareness Training Program, which standardizes watch protocols and trains personnel in marine species detection to prevent adverse impacts to marine mammal species. While in transit, ships must be alert at all times, use extreme caution and proceed at a safe speed such that the ship can take proper and effective action to avoid a collision with any marine mammals.

During mooring or UUV deployment, visual observation would start 15 minutes prior to and continue throughout the deployment within the mitigation zone of 180 ft (55 m, roughly one ship length) around the deployed mooring. Deployment will stop if a marine mammal is visually detected within the exclusion zone. Deployment will re-commence if any one of the following conditions are met: (1) The animal is observed exiting the exclusion zone, (2) the animal is thought to have exited the exclusion zone based on its course and speed, or (3) the exclusion zone has been clear from any additional sightings for a period of 15 minutes for pinnipeds and 30 minutes for cetaceans.

Ships would avoid approaching marine mammals head-on and would maneuver to maintain a mitigation zone of 500 yards (yd; 457 m) around observed cetaceans, and 200 yd (183 m) around all other marine mammals, provided it is safe to do so in ice-free waters. Ships captains and subsistence whalers would also maintain at-sea communication to avoid conflict of ship transit with hunting activity.

If a marine mammal species for which take is not authorized is encountered or observed within the mitigation zone, or a species for which authorization was granted but the authorized number of takes have been met, activities must cease. Activities may not resume until

the animal is confirmed to have left the area.

These requirements do not apply if a vessel's safety is at risk, such as when a change of course would create an imminent and serious threat to safety, person, or vessel, and to the extent that vessels are restricted in their ability to maneuver. No further action is necessary if a marine mammal other than a cetacean continues to approach the vessel after there has already been one maneuver and/or speed change to avoid the animal. Avoidance measures should continue for any observed cetacean in order to maintain a mitigation zone of 500 yd (457 m).

Based on our evaluation of the applicant's proposed measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

While underway, the ships (including non-Navy ships operating on behalf of the Navy) utilizing active acoustics will have at least one watch person during activities. Watch personnel must undertake extensive training through the Navy's Marine Species Awareness Training. Their duties may be performed in conjunction with other job responsibilities, such as navigating the ship or supervising other personnel. While on watch, personnel employ visual search techniques, including the use of binoculars, using a scanning method in accordance with the U.S. Navy Marine Species Awareness Training or civilian equivalent. A primary duty of watch personnel is to detect and report all objects and disturbances sighted in the water that may be indicative of a threat to the ship and its crew, such as debris, or surface disturbance. Per safety requirements, watch personnel also report any marine mammals sighted that have the potential to be in the direct path of the ship as a standard collision avoidance procedure.

While underway, the ships (including non-Navy ships operating on behalf of the Navy) utilizing active acoustics and towed in-water devices will have at least one watch person during activities. While underway, watch personnel must be alert at all times and have access to binoculars. Each day, the following information should be recorded:

- Vessel name;
- Watch personnel names and affiliations;
- Effort type (*i.e.,* transit or deployment); and
- Environmental conditions (at the beginning of watch personnel shift and whenever conditions changed significantly), including Beaufort Sea State and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon.

Watch personnel must use standardized data collection forms, whether electronic or hard copy, as well as distinguish between marine mammal sightings that occur during ship transit or acoustic source deployment. Upon visual observation of a marine mammal, the following information would be recorded:

- Date/time of sighting;
- Identification of animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified) and the composition of the group if there is a mix of species;
- Location (latitude/longitude) of sighting;
- Estimated number of animals (high/low/best)
- Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);
- Detailed behavior observations (*e.g.,* number of blows/breaths, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; length of time the animal was observed within the harassment zone; note any observed changes in behavior);
- Distance from ship to animal;
- Direction of animal's travel relative to the vessel
- Platform activity at time of sighting (*i.e.,* transit, deployment); and
- Weather conditions (*i.e.,* Beaufort Sea State, cloud cover).

The U.S. Navy has coordinated with NMFS to develop an overarching program plan in which specific monitoring would occur. This plan is called the Integrated Comprehensive Monitoring Program (ICMP) (Department of the Navy, 2011). The ICMP has been developed in direct response to Navy permitting requirements established through various environmental compliance efforts. As a framework document, the ICMP applies by regulation to those activities on ranges and operating areas for which the Navy is seeking or has sought incidental take authorizations. The ICMP is intended to coordinate monitoring efforts across all regions and to allocate the most appropriate level and type of effort based on a set of standardized research goals, and in acknowledgement of regional scientific value and resource availability.

The ICMP is focused on Navy training and testing ranges where the majority of Navy activities occur regularly as those areas have the greatest potential for

being impacted. ONR's ARA in comparison is a less intensive test with little human activity present in the Arctic. Human presence is limited to the deployment of sources that would take place over several weeks. Additionally, due to the location and nature of the testing, vessels and personnel would not be within the study area for an extended period of time. As such, more extensive monitoring requirements beyond the basic information being collected would not be feasible as it would require additional personnel and equipment to locate seals and a presence in the Arctic during a period of time other then what is planned for source deployment. However, ONR will record all observations of marine mammals, including the marine mammal's species identification, location (latitude and longitude), behavior, and distance from project activities. ONR will also record date and time of sighting. This information is valuable in an area with few recorded observations.

If any injury or death of a marine mammal is observed during the 2022–2023 ARA, the Navy will immediately halt the activity and report the incident to the Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator, NMFS. The following information must be provided:

- Time, date, and location of the discovery;
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal(s) was discovered (*e.g.,* deployment of moored or drifting sources or by transiting vessel).

ONR will provide NMFS OPR and AKR with a draft monitoring report within 90 days of the conclusion of each research cruise, or sixty days prior to the issuance of any subsequent IHA for this project, whichever comes first. The draft monitoring report will include data regarding acoustic source use and any mammal sightings or detection documented. The report will include the estimated number of marine mammals taken during the activity. The report will also include information on the number of shutdowns recorded. If no comments are received from NMFS within 30 days of submission of the draft final report, the draft final report will constitute the final report. If comments are received, a final report must be submitted within 30 days after receipt of comments.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to beluga whales and ringed seals, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

Underwater acoustic transmissions associated with the proposed ARA, as outlined previously, have the potential to result in Level B harassment of beluga seals and ringed seals in the form of behavioral disturbances. No serious injury, mortality, or Level A harassment are anticipated to result from these described activities. Effects on individual belugas or ringed seals taken by Level B harassment could include alteration of dive behavior and/or foraging behavior, effects to breathing rates, interference with or alteration of vocalization, avoidance, and flight. More severe behavioral responses are not anticipated due to the localized, intermittent use of active acoustic sources. However, exposure duration is likely to be short-term and individuals will, most likely, simply be temporarily displaced by moving away from the acoustic source. Exposures are, therefore, unlikely to result in any significant realized decrease in fitness for affected individuals or adverse impacts to stocks as a whole.

Arctic ringed seals are listed as threatened under the ESA. The primary concern for Arctic ringed seals is the ongoing and anticipated loss of sea ice and snow cover resulting from climate change, which is expected to pose a significant threat to ringed seals in the future (Muto *et al.,* 2021). In addition, Arctic ringed seals have also been experiencing a UME since 2019 although the cause of the UME is currently undetermined. As mentioned earlier, no mortality or serious injury to ringed seals is anticipated nor proposed to be authorized. Due to the short-term duration of expected exposures and required mitigation measures to reduce adverse impacts, we do not expect the proposed ARA to affect annual rates of ringed seal survival and recruitment that may threaten population recovery or exacerbate the ongoing UME.

A small portion of the proposed ARA study area overlaps with ringed seal critical habitat. Although this habitat contains features necessary for ringed seal formation and maintenance of subnivean birth lairs, basking and molting, and foraging, these features are also available throughout the rest of the designated critical habitat area. Displacement of ringed seals from the proposed ARA study area would likely not interfere with their ability to access necessary habitat features. Therefore, we expect minimal impacts to any displaced ringed seals as similar necessary habitat features would still be available nearby.

The proposed ARA study area also overlaps with a beluga whale migratory BIA. Due to the small amount of overlap between the BIA and the proposed ARA study area as well as the low intensity and short-term duration of acoustic sources and required mitigation measures, we expect minimal impacts to migrating belugas. Shutdown zones will reduce the potential for Level A harassment of belugas and ringed seals, as well as the severity of any Level B

harassment. The requirements of trained dedicated watch personnel and speed restrictions will also reduce the likelihood of any ship strikes to migrating belugas.

In all, the proposed ARA are expected to have minimal adverse effects on marine mammal habitat. While the activities may cause some fish to leave the area of disturbance, temporarily impacting marine mammals' foraging opportunities, this would encompass a relatively small area of habitat leaving large areas of existing fish and marine mammal foraging habitat unaffected. As such, the impacts to marine mammal habitat are not expected to impact the health or fitness of any marine mammals.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- Impacts would be limited to Level B harassment only;
- Only temporary behavioral modifications are expected to result from these proposed activities;
- Impacts to marine mammal prey or habitat will be minimal and short term.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

Subsistence hunting is important for many Alaska Native communities. A study of the North Slope villages of Nuiqsut, Kaktovik, and Utqiaġvik (formally Barrow) identified the primary resources used for subsistence and the locations for harvest (Stephen R. Braund & Associates, 2010), including terrestrial mammals (caribou, moose, wolf, and wolverine), birds (geese and eider), fish (Arctic cisco, Arctic char/Dolly Varden trout, and broad whitefish), and marine mammals (bowhead whale, ringed seal, bearded seal, and walrus). Ringed seals and beluga whales are likely located within the project area during this proposed action, yet the proposed action would not remove individuals from the population nor behaviorally disturb them in a manner that would affect their behavior more than 100km farther inshore where subsistence hunting occurs.. The permitted sources would be placed far outside of the range for subsistence hunting. The closest active acoustic source (fixed or drifting) within the proposed project site that is likely to cause Level B take is approximately 110 nm (204 km) from land. This ensures a significant standoff distance from any subsistence hunting area. The closest distance to subsistence hunting (70 nm, or 130 km) is well the largest distance from the sound sources in use at which behavioral harassment would be expected to occur (20 km) described above. Furthermore, there is no reason to believe that any behavioral disturbance of beluga whales or ringed seals that occurs far offshore (we do not anticipate any Level A harassment) would affect their subsequent behavior in a manner that would interfere with subsistence uses should those animals later interact with hunters.

In addition, ONR has been communicating with the Native communities about the proposed action. The ONR chief scientist for AMOS gave a virtual briefing on ONR research planned for 2022–2023 Alaska Eskimo Whaling Commission (AEWC) meeting in February 2022. This briefing communicated the lack of effect on subsistence hunting due to the distance of the sources from hunting areas. ONR scientists also attend Arctic Waterways Safety Committee (AWSC) and AEWC meetings regularly to discuss past, present, and future ARA. While no take is anticipated to result during transit, points of contact for at-sea communication will also be established between ship captains and whalers to avoid any conflict of ship transit with hunting activity.

Based on the description of the specified activity, distance of the study area from subsistence hunting grounds, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from ONR's proposed activities.

Peer Review of the Monitoring Plan—The MMPA requires that monitoring plans be independently peer reviewed where the proposed activity may affect the availability of a species or stock for taking for subsistence uses (16 U.S.C. 1371(a)(5)(D)(ii)(III)). Given the factors discussed above, NMFS has also determined that the activity is not likely to affect the availability of any marine mammal species or stock for taking for subsistence uses, and therefore, peer review of the monitoring plan is not warranted for this project.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with Alaska Regional Office (AKR).

NMFS is proposing to authorize take of ringed seals, which are listed under the ESA. The Permits and Conservation Division has requested initiation of section 7 consultation with the AKR for the issuance of this IHA. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to ONR for conducting their fifth year of ARA in the Beaufort and eastern Chukchi Seas from September 2022—September 2023, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: *www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed ARA. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, one-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activities section of this notice is planned or (2) the activities as described in the Description of Proposed Activities section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA).
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: July 20, 2022.

Shannon Bettridge,

Chief, Marine Mammal and Sea Turtle Conservation Division,Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–15937 Filed 7–25–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Draft Environmental Assessment for the Installation of a High Frequency Radar at Hightower Park in Satellite Beach, Florida

AGENCY: National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce.

ACTION: Notice of Availability; Request for Comments.

SUMMARY: NOAA has prepared a draft environmental assessment (EA) for the installation of a high frequency radar at Hightower Park in Satellite Beach, Florida. We are making the environmental assessment available to the public for review and comment.

DATES: Written comments must be submitted on or before August 25, 2022.

ADDRESSES: The Draft EA is available online at *https://ioos.noaa.gov/hightower-beach-park.*

If you wish to comment on the Draft EA, please send comments via email to U.S. IOOS Office at *hightowerbeachpark@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Mequela Moreno, U.S. Integrated Ocean Observing System (IOOS), Regions Budget & Policy Division, by email *mequela.moreno@noaa.gov,* by phone 240–533–9433, or by mail at 1315 East West-Highway, SSMC3, 2nd Floor, Silver Spring, MD 20910.

SUPPLEMENTARY INFORMATION: NOAA's U.S. Integrated Ocean Observing System (IOOS) Program Office has prepared a draft environmental assessment of potential impacts for the installation of a high frequency radar (HFR) at Hightower Beach Park, in the City of Satellite Beach, Florida.

The HFR would be installed south and shoreward of the parking lot at Hightower Beach Park, approximately 100 ft. (30 meters) away. Coordinates: Latitude: 28.194372° N; Longitude: 80.594403° W (WGS 84 datum).

The proposed action at Hightower Beach Park HFR installation is part of a large, on-going initiative to fill HFR coverage gaps along the southeast coastline. HFR systems measure the speed and direction of ocean surface currents in near real time. The HFR systems are managed by Southeast Coastal Ocean Observing Regional Association (SECOORA) and the Integrated Ocean Observing System (IOOS®), which is a national-regional partnership working to provide new tools and forecasts to improve safety, enhance the economy, and protect our environment. IOOS was created by the Integrated Coastal and Ocean Observation System Act of 2009 (Pub. L. 111–11), and amended by the Coordinated Ocean Observation and Research Act of 2020 (Pub. L. 116–271, Title I), codified at (33 U.S.C. 3601–3610).

Surface current mapping is integral to research, supporting oceanographic, fisheries, and meteorological forecasting activities. Surface current mapping is also vital for U.S. Coast Guard search and rescue activities, monitoring and tracking hazardous materials, monitoring water quality, including tracking harmful algal blooms, and supporting marine navigation.

IOOS proposes that the installation and operation of the HFR would have no significant impact on the environment. The EA has been prepared in accordance with the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*) and Council on Environmental Quality implementing regulations (40 CFR parts 1500–1508), as well as the Integrated Coastal and Ocean Observation System Act of 2009 (Pub. L. 111–11), as amended by the Coordinated Ocean Observation and Research Act of 2020 (Pub. L. 116–271, Title I), codified at (33 U.S.C. 3601–3610).

Carl C. Gouldman,

Director, U.S. Integrated Ocean Observing System Office, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–15897 Filed 7–25–22; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC170]

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 Pacific Fishery Management Council's (Pacific Council) Scientific and Statistical Committee's (SSC's) Groundfish Subcommittee will hold an online meeting to discuss coordination of ageing efforts to inform 2023 and 2025 groundfish stock assessments.

DATES: The online meeting will be held on Thursday, August 11, 2022, from 9 a.m. to 12 p.m., Pacific Daylight Time.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. John DeVore, Staff Officer, Pacific Council; telephone: (503) 820–2413.

SUPPLEMENTARY INFORMATION: The SSC's Groundfish Subcommittee will discuss the availability of ageing structures collected by the states and NMFS in fishery sampling and surveys that may inform stock assessments prioritized for 2023 and 2025. The SSC's Groundfish Subcommittee will recommend how ageing labs should prioritize the ageing of these structures to optimize the availability of data for 2023 and 2025 stock assessments. These recommendations will be provided to the SSC and the Pacific Council for their deliberations at their September meetings.

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

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*; (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: July 21, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–15979 Filed 7–25–22; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Publication of FY 2019 Service Contract Inventory

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of public availability of FY 2019 Service Contract Inventory.

SUMMARY: In accordance with section 734 of Division C of the Consolidated Appropriations Act of 2010, the Consumer Financial Protection Bureau (Bureau) is publishing this notice to advise the public of the availability of the FY 2019 service contract inventory. This inventory provides information on service contract actions over $25,000, which the Bureau funded during FY 2019. The information is organized by function to show how contracted resources were used by the agency to support its mission. The inventory has been developed in accordance with the guidance issued by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). The Bureau has posted its inventory on the Bureau's Open Government homepage at the following link: *https://www.consumerfinance.gov/open.*

FOR FURTHER INFORMATION CONTACT: Nikki Burley, Senior Procurement Analyst, Office of Procurement, at 202–435–0329, or *Nikki.Burley@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

Jocelyn Sutton,

Deputy Chief of Staff, Consumer Financial Protection Bureau.

[FR Doc. 2022–15962 Filed 7–25–22; 8:45 am]

BILLING CODE 4810–AM–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meetings Notice

TIME AND DATE: Friday, July 29, 2022; 10:00 a.m.

PLACE: The meeting will be held remotely.

STATUS: Commission Meeting—Closed to the Public.

MATTERS TO BE CONSIDERED: *Decisional Matter.*

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, 301–504–7479 (Office) or 240–863–8938 (Cell).

Dated: July 22, 2022.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2022–16140 Filed 7–22–22; 4:15 pm]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, July 27, 2022; 10:00–11:00 a.m.

PLACE: This meeting will be held remotely.

STATUS: Commission Meeting—Open to the Public.

MATTERS TO BE CONSIDERED: Briefing Matter: CPSC's Draft Strategic Plan 2023–2026

All attendees should pre-register for the Commission meeting using the following link: *https://cpsc.webex.com/cpsc/onstage/g.php?MTID=e7e1a85f0cc0d441beb2fbb9bfaa136de.*

After registering you will receive a confirmation email containing information about joining the meeting.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, 301–504–7479 (Office) or 240–863–8938 (Cell).

Dated: July 21, 2022.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2022–16057 Filed 7–22–22; 11:15 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2022–HQ–0015]

Proposed Collection; Comment Request

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the U.S. Army Training and Doctrine Command, G3/5/7 announces a proposed public information collection and seeks public comment on the

provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the US Army G–1, Directorate of Personnel Management, ATTN: Scott Wood, ACQUIRE Systems Manager, 1D367, 300 Pentagon, Washington DC 20301, email to *scott.e.wood3.civ@army.mil* or call (730) 695–7520.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Army Recruiting Information: Army Recruiting Information Support System and Accessions Information Environment; OMB Control Number 0702–AAIE.

Needs and Uses: The required collection of information provides U.S. Army field recruiters with an automated tool to collect information on all prospective U.S. Army, Army Reserve, Army National Guard, Army Cadet Command, U.S. Army Military Academy candidates, enlistees, officers and health profession personnel voluntarily requesting entrance into active duty. The required information collected is used to create the initial personnel record/data to prescreen perspective applicants, line officers and health professionals to determine if they meet established mandated qualifications for induction and processing into the U.S. Army. The information is also collected to process security clearances for those individuals requiring clearances for sensitive and classified positions.

Affected Public: Individuals or households.

Annual Burden Hours: 1,000,000.

Number of Respondents: 250,000.

Responses per Respondent: 1.

Annual Responses: 250,000.

Average Burden per Response: 4 hours.

Frequency: On occasion.

The respondents are recruiting applicants (accessions) which includes, civilians, veterans and cross component recruits. Other collection instruments/documents are completed by applicants and recruiters into the system of record as applicable to their recruiting and application purposes. All completed instruments of the collection reside in the system of record which has safeguards in place to protect privacy information. Both the electronic online Army Recruiting Information Support System (ARISS) and Accessions Information Environment (AIE) systems provide a comprehensive integration, interface and standardization of all programs that manage personnel resources in support of recruiting and collecting personnel private information to induct Army applicants into the U.S. Army. The current (legacy) system ARISS, will eventually be subsumed by the emergent AIE system.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15951 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0018]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by August 25, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Office of Local Defense Community Cooperation Economic Adjustment Data System; OMB Control Number 0704–0625.

Type of Request: Extension.

Number of Respondents: 62.

Responses per Respondent: 6.

Annual Responses: 372.

Average Burden per Response: 100 minutes.

Annual Burden Hours: 620 hours.

Needs and Uses: The Office of Local Defense Community Cooperation in coordination with other Federal Agencies, delivers a program of technical and financial assistance to enable states and communities to plan and carry out civilian responses to workforce, business, and community needs arising from Defense actions; cooperate with military installations and leverage public and private capabilities to deliver public infrastructure and services to enhance the military mission and achieve facility and infrastructure savings; and increase military, civilian, and industrial readiness and resiliency, and support military families. The Economic Adjustment Data System supports this mission by providing a platform for authorized grant applicants to submit their application packages, and for grant awardees to submit quarterly or semi-annual performance reports. Respondents will be States, U.S. Territories, counties, municipalities, other political subdivisions of a state, special purpose units of a state or local government, other instrumentalities of a

state or local government, and tribal nations supporting a military installation or the defense industrial base.

Affected Public: State, Local, or Tribal Government; Business or other for-profit; Not-for-profit Institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

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

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: July 21, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15958 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0084]

Proposed Collection; Comment Request

AGENCY: The Office of the Under Secretary of Defense for Research and Engineering (OUSD(R&E)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Research and Engineering announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to SMART Program Office, 4800 Mark Center Drive, Suite 17C08, Alexandria, VA, 22350–3600, Dr. Brandon Cochenour, 240–526–1123.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Science, Mathematics and Research for Transformation Scholarship Program; DD Forms 3067–2, 3067–4, 3067–7, 3067–8, 3067–9, 3067–11, 3067–12, 3067–13, 3067–15; OMB Control Number 0704–0466.

Needs and Uses: Science, Mathematics and Research for Transformation Scholarship Program (SMART) is designed to increase the number of new civilian science, technology, engineering, and mathematics (STEM) entrants to the DoD. Additionally, the SMART Program develops and retains current DoD civilian STEM employees that are critical to the national security functions of the DoD and are needed in the DoD's workforce. SMART awards scholarships, ranging from 1.5 to 5 years, to undergraduate and graduate level students pursuing a degree in one of 21 technical disciplines. Upon graduation, scholars fulfill a service commitment with the DoD facility that nominated the scholar for an award. The information collection activity under review is a statutory and functional requirement necessary to administer the scholarship program.

Affected Public: Individuals or households.

Annual Burden Hours: 31,920.

Number of Respondents: 2,800 (a percentage of respondents complete one or multiple instruments).

Responses per Respondent: 3.8.

Annual Responses: 10,640.

Average Burden per Response: 3 hours.

Frequency: On occasion.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15942 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–HA–0090]

Proposed Collection; Comment Request

AGENCY: The Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Health Agency, 7700 Arlington Blvd., Falls Church, VA 22042, Terry McDavid, 703–681–3645.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Unmet Needs of Transgender Military Patients at Madigan Army Medical Center; OMB Control Number 0720–MAMC.

Needs and Uses: This collection is necessary in order to identify the unmet needs of transgender patients at Madigan Army Medical Center. Policy changes (and subsequent reversal) regarding transgender military members has limited transgender patient care and has led to confusion around services provided. Military providers do not generally have experience or special training in caring for the transgender population and may lack the expertise needed for optimal patient care. This activity will develop and distribute an anonymous survey to accomplish the goal of identifying these unmet needs in order to find areas for improvement and optimize transgender care at Madigan Army Medical Center.

Affected Public: Federal Government.

Annual Burden Hours: 59.

Number of Respondents: 59.

Responses per Respondent: 1.

Annual Responses: 59.

Average Burden per Response: 1 hour.

Frequency: On occasion.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15949 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0086]

Proposed Collection; Comment Request

AGENCY: Defense Security Cooperation Agency (DSCA), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Security Cooperation Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to DSCA, Defense Security Cooperation Agency, 2800 Defense Pentagon Washington, DC 20301–2800, Joshua Dill, 717–743–1026.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: The GlobalNET Collection; OMB Control Number 0704–0558.

Needs and Uses: The purpose of the GlobalNET system is to provide a collaborative social networking environment/capability where students, alumni, faculty, partners, and other community members and subject matter experts can find relevant and timely information about pertinent subject matter experts and conduct required training. GlobalNET also collects information on students in order to allow regional center personnel to manage students while enrolled at regional centers.

Affected Public: Individuals and households.

Annual Burden Hours: 500.

Number of Respondents: 6,000.

Responses per Respondent: 1.

Annual Responses: 6,000.

Average Burden per Response: 5 minutes.

Frequency: On occasion.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15947 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0085]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Logistics Agency (DLA) announces a proposed public information collection and seeks public

comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Logistics Agency Headquarters, ATTN: Ms. Nina Beshai, J62BK Information Operations, 8725 John Kingman Road, Fort Belvoir, VA 22060–6221, or call (571) 767–9810.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DLA Police Center Records; DLA Form 635; OMB Control Number 0704–0514.

Needs and Uses: The DLA Police Center system houses data of civilian and military personnel of DLA, contractor employees, and other persons who have committed or are suspected of having committed any criminal act (felony or misdemeanor), as well as any violations of laws, regulations, or ethical standards on DLA-controlled activities or facilities. The information is used by DLA police officers, DLA installation support offices, and the DLA Office of General Counsel (OGC) to monitor progress of cases and to develop non-personal statistic data on crime and criminal investigative support for the future. DLA OGC also uses the data to review cases, determine appropriate legal action, and coordinate on all available remedies. Information is released to DLA managers who use the information to determine actions required to correct the causes of loss and to take appropriate action against DLA employees or contractors in cases of their involvement. Records are also used by DLA police to monitor the progress of incidents, identify crime-conducive conditions, and prepare crime vulnerability assessments.

Affected Public: Individuals or households.

Annual Burden Hours: 1,000.

Number of Respondents: 2,000.

Responses per Respondent: 1.

Annual Responses: 2,000.

Average Burden per Response: 30 minutes.

Frequency: On occasion.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15948 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0087]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Human Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571–372–2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DoD Sexual Assault Prevention and Response Office Victim-Related Inquiries; DD Form 2985, DD Form 2985–1; OMB Control Number 0704–0565.

Needs and Uses: This information collection requirement is necessary to facilitate a timely response and appropriate resolution to inquiries from DoD sexual assault victims/survivors, support personnel and others. Collection of this information is used to support victims and survivors of sexual assault in their recovery and to maintain a database of inquiries that documents the nature and status of inquiries in order to provide adequate follow-up services and inform sexual assault prevention and response program and policy improvements while promoting

victim recovery. Military sexual assault victims, parents, other family members, and friends requesting assistance can contact the Sexual Assault Prevention and Response Office (SAPRO) by completing the DD Form 2985, ''Department of Defense Sexual Assault Prevention and Response Office Request for Assistance.'' After receiving permission from the requesting individual, the request for assistance is referred to the appropriate agency for action to facilitate a resolution.

Affected Public: Individuals or households.

Annual Burden Hours: 75 hours.

Number of Respondents: 150.

Responses per Respondent: 1.

Annual Responses: 150.

Average Burden per Response: 30 minutes.

Frequency: On occasion.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15946 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0088]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Logistics Agency (DLA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to DLA Installation Management at Battle Creek Hart-Dole-Inouye Federal Center, Room 1–2–3 74 Washington Avenue North, Battle Creek, MI 49037, ATTN: Ms. Pamela Moutz, or call 269–961–5107.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Qualified Facility List Application; DLA Form 2507; OMB Control Number 0704–AQFL.

Needs and Uses: The information collected via DLA Form 2507 will be used to validate hazardous waste disposal facilities around the world. Prior to the U.S. Government sending hazardous waste to a disposal facility, the facility must undergo a vetting process to ensure they are properly permitted, insured, and operating within local, state, and/or national regulations.

Affected Public: Businesses or other for-profit.

Annual Burden Hours: 25.

Number of Respondents: 250.

Responses per Respondent: 1.

Annual Responses: 250.

Average Burden per Response: 6 minutes.

Frequency: As required.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15944 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0089]

Proposed Collection; Comment Request

AGENCY: Chairman of the Joint Chiefs of Staff (CJCS), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Chairman of the Joint Chiefs of Staff, J7 announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments,

please write to Deployable Training Division, J7, Joint Chiefs of Staff, 116 Lakeview Parkway, Suffolk, VA 23435, ATTN: Lieutenant Colonel Ryan Little, or call 571–256–7397.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Survey of Retired General and Flag Officers; OMB Control Number 0704–RGFO.

Needs and Uses: During the previous legislative proposal season, counsel recommended that prior to approval of the legislative proposal, the agency provide evidence that retired three and four-star flag and general officers did not apply as a DoD Highly Qualified Expert-Senior Mentors due to the requirement to file an annual public 278 financial disclosure. The best evidence is a survey of recent retirees of the population.

Affected Public: Individuals or households.

Annual Burden Hours: 5.

Number of Respondents: 30.

Responses per Respondent: 1.

Annual Responses: 30.

Average Burden per Response: 10 minutes.

Frequency: One-time.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15943 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0083]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Intelligence and Security (OUSD(I&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Counterintelligence and Security Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Counterintelligence and Security Agency, Office of Industrial Policy and Programs; 27130 Telegraph Road, Quantico, VA 22134, ATTN: Ms. Laura Aghdam, or call 571–305–6856.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Security Agreement; DD Form 441, DD Form 441–1; OMB Control Number 0704–0194.

Needs and Uses: This information collection requirement is necessary for inspecting and monitoring the contractors, licensees, and grantees who require or will require access to, or who store or will store classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees.

Affected Public: Individuals or households.

Annual Burden Hours: 1608.4.

Number of Respondents: 4,021.

Responses per Respondent: 1.

Annual Responses: 4,021.

Average Burden per Response: 24 minutes.

Frequency: On occasion.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15941 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0041]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by August 25, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Education Activity Research Request Program; DoDEA Form 1304.01–F1; OMB Control Number 0704–0457.

Type of Request: Revision.

Number of Respondents: 50.

Responses per Respondent: 1.

Annual Responses: 50.

Average Burden per Response: 1 hour.

Annual Burden Hours: 50 hours.

Needs and Uses: The Department of Defense Education Activity (DoDEA) Research Study Request form is administered annually and is used to conduct research involving DoDEA schools, teachers, principals, students, and parents. DoDEA receives requests from researchers both internal to DoDEA

as well as outside the Federal government or DoD, to conduct research studies in DoDEA schools and districts. This information collection is needed to aid in the systematic and consistent collection of information on proposed research in accordance with guidelines established in DoDEA Administrative Instruction 1304.01, ''Research Request Program.''

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

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

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: July 21, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15957 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2022–HQ–0023]

Proposed Collection; Comment Request

AGENCY: Department of the Navy, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Navy announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the United States Naval Academy, 121 Blake Road, RM 311 Annapolis, MD 21402–1300, ATTN: Ms. Shannon Campbell, or call 410–293–1550.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Naval Academy Candidate Application Package; USNA Forms 1110/7, 5710/1, 5710/2, 1531/3, 1110/5, 1110/21, 5500/31, 1531/11, 1531/16, 1531/178, and 1531/17; OMB Control Number 0703–0036.

Needs and Uses: This information requirement is used to determine the eligibility, competitive standing, and the scholastic and leadership potential of candidates for an appointment to the United States Naval Academy (USNA). Prior performance, including academic achievements, involvement in extracurricular activities and performance in leadership positions, has been found to be an excellent predictor of success. Without this information, the Naval Academy's ability to recruit qualified candidates will be seriously impacted. An analysis of the information collected is made by the Admissions Board in order to gauge the qualifications of individual candidates. Respondents are applicants for admission to the USNA, persons interested in applying for admission to the USNA, school officials for those applicants, Chain of Command officials for active duty applicants, person's providing recommendations for applicants, Blue and Gold Officers, Embassy or Naval Attachés for international applicants from other countries, and local law enforcement officials.

Affected Public: Individuals or households.

Annual Burden Hours: 135,484.

Number of Respondents: 114,188.

Responses per Respondent: 1.

Annual Responses: 114,188.

Average Burden per Response: 71.19 minutes.

Frequency: As required.

Dated: July 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–15950 Filed 7–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0067]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Guaranty Agency Financial Report

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before August 25, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under

''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Guaranty Agency Financial Report.

OMB Control Number: 1845–0026.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 432.

Total Estimated Number of Annual Burden Hours: 23,760.

Abstract: The Department of Education (ED) is requesting renewal by extension of the information collection 1845–0026 for the Guaranty Agency Financial Report. There has been no change to the underlying statute or regulations.

The Guaranty Agency Financial Report is used by a guaranty agency to request payments of reinsurance for defaulted student loans; make payments for amounts due ED, for collections on default and lender of last resort loan (default) claims on which reinsurance has been paid and for refunding amounts previously paid for reinsurance claims. The form is also used to determine required reserve levels for agencies; and to collect debt information as required for the ''Report on Accounts and Loans Receivable Due from the Public,'' SF 220–9 (Schedule 9 Report) as required by the U.S. Department of Treasury.

Dated: July 21, 2022.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–15960 Filed 7–25–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Intent Regarding Bipartisan Infrastructure Law Support for Resilient and Efficient Building Energy Code Implementation

AGENCY: Office Energy Efficiency and Renewable Energy, Building Technologies Office, Department of Energy (DOE).

ACTION: Notice of intent.

SUMMARY: The U.S. Department of Energy (DOE) issued a Notice of Intent (NOI) to issue a Funding Opportunity Announcement (FOA) entitled ''Building Energy Codes, Resilient and Efficient Codes Implementation'' in accordance with the Bipartisan Infrastructure Law (BIL). The aim of this anticipated FOA is to support successful, widespread, and sustained implementation of updated building energy codes by states, local governments, and across the U.S. and range of affected stakeholders.

DATES: The NOI was issued on July 21, 2022.

ADDRESSES: The NOI was issued via the EERE Exchange [1] system available at *https://eere-exchange.energy.gov/.*

FOR FURTHER INFORMATION CONTACT: Jeremy Williams, (202) 441–1288, *jeremy.williams@ee.doe.gov.* Further information is available at *https://www.energycodes.gov/RECI-codes-workshop.*

SUPPLEMENTARY INFORMATION: Section 40511 of the BIL [2] provides $225 million in funding supporting resilient and efficient building codes, and directs the Secretary of Energy to establish a competitive program enabling sustained cost-effective implementation of updated building energy codes. In accordance with Section 40511, DOE intends to issue a Funding Opportunity Announcement (FOA) entitled ''Building Energy Codes, Resilient and Efficient Codes Implementation''. The aim of this anticipated FOA is to support successful, widespread and sustained implementation of updated building energy codes by states, local governments, and across the U.S. and range of affected stakeholders. More information is available via the DOE Building Energy Codes Program at *https://www.energycodes.gov/RECI-codes-workshop.*

DOE previously published, on April 18, 2022, in the **Federal Register** a request for information (RFI) (DE–FOA–0002755) and held a public workshop related to Section 40511 of the BIL preceding this Notice. *See* 87 FR 22874. Through the RFI, DOE requested public input regarding the solicitation process and structure of a potential FOA, considering a range of issues and approaches which enable sustained, cost-effective implementation of updated building energy codes, and in accordance with Section 40511. The RFI was issued on April 12, 2022, and associated public workshop was held on April 27, 2022. More information is available at: *https://www.energycodes.gov/RECI-codes-workshop.*

Signing Authority

This document of the Department of Energy was signed on July 21, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters

[1] The DOE Office of Energy Efficiency & Renewable Energy (EERE) issues funding opportunities and related announcements through the EERE Funding Opportunity Exchange system.

[2] Infrastructure Investment and Jobs Act, Public Law 117–58 (November 15, 2021). *https://www.congress.gov/bill/117th-congress/house-bill/3684.* This NOI uses the more common name ''Bipartisan Infrastructure Law''.

the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 21, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022–15976 Filed 7–25–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6972–033]

Ampersand Hollow Dam Hydro LLC; Notice Soliciting Applications

On April 29, 2021, Ampersand Hollow Dam Hydro LLC (Ampersand), licensee for the Hollow Dam Hydroelectric Project No. 6972, filed a pre-application document (PAD) and notice of its intent (NOI) to file an application for a subsequent license for the 1,060-kilowatt project pursuant to section 15(b)(1) of the Federal Power Act (FPA). On the same date, Ampersand filed a request to use the Commission's Traditional Licensing Process, which the Director, Division of Hydropower Licensing, approved on June 25, 2021. On June 27, 2022, Ampersand filed notice of the withdrawal of its NOI and PAD, indicating it is no longer seeking a subsequent license for the project.

The project is located on the West Branch Oswegatchie River in the town of Fowler in St. Lawrence County, New York. The principal project works consist of: (a) a 350.5-foot-long concrete gravity dam; (b) a reservoir with a surface area of 16 acres and storage volume of 220 acre-feet; (c) two vertical submersible hydraulic turbine-generator units; (d) a concrete intake-powerhouse structure; (e) a tailrace; (f) a 200-foot-long, 2.3-kilovolt (kV) transmission line; (g) a 2.4-kV generator bus; and (h) a 2.4/34.5-kV step-up transformer. Ampersand estimates the average annual generation of the project to be 3,900 megawatt-hours.

Pursuant to Rule 216(b) of the Commission's Rules of Practice and Procedure,[1] a withdrawal of a pleading is effective at the end of 15 days from the date of filing the notice of withdrawal. No motion in opposition to the notice of withdrawal has been filed, and the Commission has taken no action to disallow the withdrawal; thus, the withdrawal became effective on July 12, 2022.

Any party interested in filing a license application for a subsequent license for a project must first file a NOI[2] and PAD.[3] Although the Integrated Licensing Process (ILP) is the default pre-filing process, section 5.3(b) of the Commission's regulations allows a potential license applicant to request to use alternative licensing procedures when it files its NOI.[4]

This notice sets a deadline of 120 days from the date of this notice for interested applicants, other than the existing licensee, to file NOIs, PADs, and requests to use an alternative licensing process as discussed above.

In the event that no other applicant files an application for a license by April 30, 2024, the current licensee will be provided with written notice that no timely application for the project has been filed.[5] Within 90 days of such written notice, the current licensee must file a schedule for the filing of a surrender application for the project.[6]

Questions concerning this notice should be directed to Claire Rozdilski, (202) 502–8259 or *claire.rozdilski@ferc.gov.*

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15999 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.216(b) (2021).

[2] 18 CFR 5.5 (2021).

[3] 18 CFR 5.6 (2021).

[4] 18 CFR 5.3(b) (2021).

[5] 18 CFR 16.26(a) (2021).

[6] 18 CFR 16.26(b) (2021).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2413–000]

PGR 2021 Lessee 9, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PGR 2021 Lessee 9, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15994 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2405–000]

PGR 2021 Lessee 15, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PGR 2021 Lessee 15, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15986 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2400–000]

PGR 2021 Lessee 11, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PGR 2021 Lessee 11, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15990 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2421–000]

SR DeSoto I, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR DeSoto I, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214

of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15983 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2955–011]

City of Watervliet; Notice of Denial of Water Quality Certification

On February 28, 2020, the City of Watervliet (the City) filed an application for a license for the Normanskill Hydroelectric Project (project) in the above captioned docket. The City filed with the New York State Department of Environmental Conservation (New York DEC) a request for water quality certification for the project under section 401(a)(1) of the Clean Water Act on July 12, 2021. On July 7, 2022, the New York DEC denied certification for the project. Pursuant to 40 CFR 121.8, we are providing notice that New York DEC's denial satisfies the requirements of 40 CFR 121.7(e).

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16000 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2410–000]

Sonny Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Sonny Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16002 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2403–000]

PGR 2021 Lessee 12, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PGR 2021 Lessee 12, LLC's application for market-based rate authority, with an

accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15988 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2426–000]

SR McKellar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR McKellar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15995 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2425–000]

SR Clay, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR Clay, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16006 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2401–000]

Cabin Creek Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Cabin Creek Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (http://www.*ferc*.gov) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15989 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21–62–000.
Applicants: Uniper Global Commodities North America LLC.
Description: Refund Report: UGCNA Refund Report 2022.07.20 to be effective N/A.
Filed Date: 7/20/22.
Accession Number: 20220720–5069.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2429–000.
Applicants: Entergy Nuclear Palisades, LLC.
Description: Tariff Amendment: Entergy Nuclear Palisades, LLC, MBR Tariff Cancellation to be effective 7/20/2022.
Filed Date: 7/19/22.
Accession Number: 20220719–5181.
Comment Date: 5 p.m. ET 8/9/22.

Docket Numbers: ER22–2430–000.
Applicants: Entergy Nuclear Power Marketing, LLC.
Description: Tariff Amendment: Entergy Nuclear Power Marketing, LLC, MBR Tariff Cancellation to be effective 7/20/2022.
Filed Date: 7/19/22.
Accession Number: 20220719–5183.
Comment Date: 5 p.m. ET 8/9/22.

Docket Numbers: ER22–2431–000.
Applicants: The United Illuminating Company.
Description: § 205(d) Rate Filing: Schedule 20A Phase I/II HVDC–TF Service Agreements for the Resale, Reassignment to be effective 12/31/9998.
Filed Date: 7/19/22.
Accession Number: 20220719–5184.
Comment Date: 5 p.m. ET 8/9/22.

Docket Numbers: ER22–2432–000.
Applicants: The United Illuminating Company.
Description: § 205(d) Rate Filing: Schedule 20A Phase I/II HVDC–TF Service Agreements for the Resale, Reassignment to be effective 12/31/9998.
Filed Date: 7/19/22.
Accession Number: 20220719–5189.
Comment Date: 5 p.m. ET 8/9/22.

Docket Numbers: ER22–2433–000.
Applicants: Central Maine Power Company.
Description: § 205(d) Rate Filing: Schedule 20A Phase I/II HVDC–TF Service Agreements for the Resale, Reassignment to be effective 12/31/9998.

Filed Date: 7/19/22.
Accession Number: 20220719–5190.
Comment Date: 5 p.m. ET 8/9/22.

Docket Numbers: ER22–2434–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 6077; Queue Nos. AA1–146/AA2–030 to be effective 5/12/2021.
Filed Date: 7/20/22.
Accession Number: 20220720–5011.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2435–000.
Applicants: Midcontinent Independent System Operator, Inc., American Transmission Company LLC.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2022–07–20_SA 3871 ATC-Allete PSA to be effective 8/30/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5021.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2436–000.
Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2022–07–20_SA 2880 Att A-Proj Spec No. 9–WVPA-Maroa to be effective 9/19/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5025.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2437–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, SA No. 4963; Queue No. V4–027/AC2–170 to be effective 3/12/2018.
Filed Date: 7/20/22.
Accession Number: 20220720–5034.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2438–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original NSA No. 6550; Queue No. AD2–163 to be effective 6/20/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5054.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2439–000.
Applicants: Indiana Crossroads Wind Farm LLC.
Description: Baseline eTariff Filing: Shared Facilities Agreement—Meadow Lake to be effective 7/20/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5055.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2440–000.
Applicants: Alabama Power Company, Georgia Power Company, Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: Aragon Energy Storage LGIA Filing to be effective 7/20/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5073.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2441–000.
Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2022–07–20_SA 2880 Att A- Proj Spec No. 10–WVPA-Troy Grove Viper to be effective 9/19/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5081.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2442–000.
Applicants: Tidal Energy Marketing Inc.
Description: Tariff Amendment: Notice of Cancellation to be effective 7/21/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5086.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2443–000.
Applicants: Virginia Electric and Power Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Virginia Electric and Power Company submits tariff filing per 35.13(a)(2)(iii: Dominion submits revisions to Formula Rate Template, Attachment H–16A to be effective 1/1/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5136.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2444–000.
Applicants: ITC Midwest LLC.
Description: § 205(d) Rate Filing: Filing of Three Agreements with Independence Light & Power Company to be effective 9/19/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5140.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: ER22–2445–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original NSA, SA No. 6537; Queue No. B34 to be effective 6/20/2022.
Filed Date: 7/20/22.
Accession Number: 20220720–5143.
Comment Date: 5 p.m. ET 8/10/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene 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 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15998 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meetings

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b: *Agency Holding Meeting:* Federal Energy Regulatory Commission.

DATE AND TIME: July 28, 2022, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426.

STATUS: Open to the public.[1]

MATTERS TO BE CONSIDERED: Agenda.

* *Note*—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's website at *https://elibrary.ferc.gov/eLibrary/search* using the eLibrary link.

[1] The Commission Meeting is open for attendance from the public. Members of the public who are interested in attending the meeting must adhere to safety and health protocols detailed on the Commission's website to be granted admission into the building. Information on these protocols can be accessed at *http://www.ferc.gov.*

1092ND—MEETING, OPEN MEETING

[July 28, 2022, 10:00 a.m.]

Item No.	Docket No.	Company
	ADMINISTRATIVE	
A-1	AD22–1–000	Agency Administrative Matters.
A-2	AD22–2–000	Customer Matters, Reliability, Security and Market Operations.
	ELECTRIC	
E-1	RM22–13–000	Credit-Related Information Sharing in Organized Wholesale Electric Markets.
E–2	EL22–62–000	California Independent System Operator Corporation.
	EL22–63–000	ISO New England Inc.
	EL22–64–000	New York Independent System Operator, Inc.
	EL22–65–000 (not consolidated)	Southwest Power Pool Inc.
E-3	RM21–11–000	Accounting and Reporting Treatment of Certain Renewable Energy Assets.
E–4	EL19–58–007	PJM Interconnection, L.L.C.
	ER19–1486–004	
E-5	ER21–998–002	Midway Sunset Cogeneration Company.
E-6	IN79–6–000	Form 580—Interrogatory on Fuel and Energy Purchase Practices and Sierra Pacific Power Company.
E–7	EL22–31–000	Northern Maine Independent System Administrator, Inc. v. ISO New England Participating Transmission Owners Administrative Committee.
	MISCELLANEOUS	
M–1	RM22–20–000	Duty of Candor.
	GAS	
G–1	OR19–14–000	MPLX Ozark Pipe Line LLC.
	HYDRO	
H-1	P–14635–001	Village of Gouverneur, New York.
H–2	P–77–312	Pacific Gas and Electric Company.
	CERTIFICATES	
C–1	CP95–35–002	EcoEléctrica, L.P.
C–2	CP21–470–000	Freeport LNG Development, L.P., FLNG Liquefaction, LLC, FLNG Liquefaction 2, LLC, and FLNG Liquefaction 3, LLC.
C–3	CP20–484–001	ANR Pipeline Company.
C–4	CP21–29–000	Gas Transmission Northwest LLC.
C–5	CP21–179–001	Nopetro LNG, LLC.
C–6	CP14–517–001	Golden Pass LNG Terminal LLC.
C–7	CP15–554–010	Atlantic Coast Pipeline, LLC.
	CP15–555–008	Eastern Gas Transmission and Storage, Inc.

A free webcast of this event is available through *http://ferc.capitolconnection.org/*. Anyone with internet access who desires to view this event can do so by navigating to *www.ferc.gov*'s Calendar of Events and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the DC area and via phone bridge for a fee. If you have any questions, visit *http://ferc.capitolconnection.org/* or contact Shirley Al-Jarani at 703–993–3104.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters, but will not be telecast through the Capitol Connection service.

Issued: July 21, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16112 Filed 7–22–22; 4:15 pm]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2404–000]

Gunsight Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Gunsight Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15987 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket Nos.	File date	Presenter or requester
Prohibited:		
NONE.		
Exempt:		
CP21–57–000	7–20–2022	U.S. Congress.[1]

[1] Representatives David B. McKinley, Carol D. Miller, Senators Joe Manchin III, and Shelley Moore Capito.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15992 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2407–000]

PGR 2021 Lessee 19, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PGR 2021 Lessee 19, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16003 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2424–000]

SR Bell Buckle, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR Bell Buckle, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

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In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15984 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2955–011]

City of Watervliet; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for license for the Normanskill Hydroelectric Project, located on the Normans Kill in the Town of Guilderland, in Albany County,

New York, and has prepared an Environmental Assessment (EA) for the project. The project does not occupy federal land.

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208-3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/eSubscription.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 45 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2955–011.

For further information, contact Woohee Choi at (202) 502–6336 or *woohee.choi@ferc.gov.*

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16004 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2423–000]

SR DeSoto I Lessee, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR DeSoto I Lessee, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15981 Filed 7–25–22; 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: RP22–1059–000.

Applicants: Dauphin Island Gathering Partners.

Description: Cash Out Report for 2022 of Dauphin Island Gathering Partners.

Filed Date: 7/19/22.

Accession Number: 20220719–5218.

Comment Date: 5 p.m. ET 8/1/22.

Docket Numbers: RP22–1060–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Compliance filing: Rate Schedules GSS & LSS EGTS Penalty Flow Through Refund Report to be effective N/A.

Filed Date: 7/20/22.

Accession Number: 20220720–5004.

Comment Date: 5 p.m. ET 8/1/22.

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.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at:*http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15997 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2411–000]

PGR 2021 Lessee 13, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PGR 2021 Lessee 13, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16001 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2428–000]

SR McKellar Lessee, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR McKellar Lessee, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16005 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2422–000]

SR Turkey Creek, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR Turkey Creek, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15980 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2399–000]

Phobos Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Phobos Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15991 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2406–000]

Allora Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Allora Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and

385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15985 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2427–000]

SR Cedar Springs, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR Cedar Springs, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15993 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2412–000]

Bulldog Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Bulldog Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 9, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling

link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–15996 Filed 7–25–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R09–OAR–2022–0360; FRL–9787–01–R9]

Clean Air Act Grant; Ventura County Air Pollution Control District; Opportunity for Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed action; determination with request for comments and notice of opportunity for public hearing.

SUMMARY: The EPA is proposing to determine that the reduction in expenditures of recurrent non-Federal funds for the Ventura County Air Pollution Control District (''VCAPCD'' or ''District'') in support of its continuing air program under section 105 of the Clean Air Act (CAA) for the calendar year 2021 are a result of non-selective reductions in expenditures. This determination, when final, will permit the VCAPCD to receive grant funding for fiscal year (FY) 2022 from the EPA under section 105 of the CAA.

DATES: Comments and/or requests for a public hearing must be received by the EPA at the address stated below on or before August 25, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2022–0360 at *https://www.regulations.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*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Proprietary Business Information (PBI) or 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 (*e.g.,* 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 PBI/CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Roberto Gutierrez, EPA Region IX, Grants and Program Integration Office, Air and Radiation Division, 75 Hawthorne Street, San Francisco, CA 94105; phone at (415) 947–4276 or email address at *gutierrez.roberto@epa.gov.*

SUPPLEMENTARY INFORMATION: Section 105 of the CAA provides grant funding to air pollution control agencies for the prevention and control of air pollution or implementation of national primary and secondary ambient air quality standards. In accordance with 40 CFR 35.145(a), the Regional Administrator may provide air pollution control agencies up to three-fifths of the approved costs of implementing programs for the prevention and control of air pollution. CAA Section 105 grants require a cost share (also referred to as a match requirement) of 40%. Program activities relevant to the match consist of both recurring and non-recurring (unique, one-time only) expenses. In addition, air pollution control agencies must meet a maintenance of effort (MOE) requirement in accordance with section 105(c)(1) of the CAA, 42 U.S.C. 7405.

The MOE provision requires that an eligible agency spend at least the same dollar level of funds as it did in the previous grant year for the costs of recurring activities. Specifically, section 105(c)(1) of the CAA, 42 U.S.C. 7405(c)(1), provides that, ''No agency shall receive any grant under this section during any fiscal year when its expenditures of non-Federal funds for recurrent expenditures for air pollution control programs will be less than its expenditures were for such programs during the preceding fiscal year.'' However, pursuant to CAA section 105(c)(2), 42 U.S.C. 7405(c)(2), the EPA may still award a grant to an agency not meeting the requirements of section 42 U.S.C. 7405(c)(1), ''. . . if the Administrator, after notice and opportunity for public hearing, determines that a reduction in expenditures is attributable to a non-selective reduction in the expenditures in the programs of all Executive branch agencies of the applicable unit of Government.'' These statutory requirements are repeated in the EPA's implementing regulations at 40 CFR 35.140–35.148. The EPA issued a memorandum dated September 30, 2011, entitled ''Updated Information for Determining a Non-Selective Reduction'' with guidance to recipients on what constitutes a nonselective reduction. In consideration of the legislative history, the guidance clarified that a non-selective reduction does not necessarily mean that each executive branch agency needs to be reduced in equal proportion. However, it must be clear to the EPA, from the weight of evidence, that a recipient's CAA-related air program is not being disproportionately impacted or singled out for a reduction.

A section 105 grant recipient must submit a final federal financial report no later than 90 days from the close of its grant period that documents all of its federal and non-federal expenditures for the completed period. The recipient seeking an adjustment to its MOE for that period must provide the rationale and the documentation necessary to enable the EPA to determine that a nonselective reduction has occurred. In order to expedite that determination, the

recipient must provide details of the budget action and the comparative fiscal impacts on all the jurisdiction's executive branch agencies, and the recipient's air program. The recipient needs to identify any executive branch agencies or programs that should be excepted from comparison and explain why. The recipient must provide evidence that the air program is not being singled out for a reduction or being disproportionately reduced. Documentation in key areas is needed including budget data specific to the recipient's air program, and comparative budget data between the recipient's air program, the agency containing the air program, and the other executive branch agencies. The EPA may also request information from the recipient about how impacts on its program operations will affect its ability to meet its CAA obligations and requirements, and documentation that explains the cause of the reduction, such as legislative changes or the issuance of a new executive order.

In FY 2021, the EPA awarded the VCAPCD $1,106,518, which represented approximately 10% of the VCAPCD budget. In FY2022, the EPA intends to award the VCAPCD $1,115,038, which represents approximately 12% of the VCAPCD budget.

VCAPCD's final federal financial report for FY2020 indicated that VCAPCD's MOE level was $6,055,144. VCAPCD's final federal financial report for FY2021 indicates that VCAPCD's expenditure on recurrent activities is $5,620,253. That level of expenditure is not sufficient to meet the MOE requirements for FY2021 under section 105 because it is not equal to or greater than the MOE for the previous fiscal year.

In order for the VCAPCD to be eligible to receive its FY2022 CAA section 105 grant, the EPA must make a determination (after notice and an opportunity for a public hearing) that the reduction in expenditures from 2020 to 2021 is attributable to a non-selective reduction in the expenditures in the programs of the VCAPCD.

The VCAPCD is a single-purpose air pollution control agency. It is the unit of government for CAA section 105(c)(2) purposes.

On February 7, 2022, the VCAPCD submitted a request to the EPA seeking a reduction for the required MOE for FY2021. The District provided supplemental information pertaining to its request on June 1, 2022. The VCAPCD explained that it was unable to meet its MOE requirement due to a decrease in reoccurring services and supplies expenses, particularly rent payments. VCAPCD was renting office space up until mid-2021 when they moved into a building they purchased to serve as their permanent office space. In FY2020 the District paid $626,800 in rent as a recurring cost. In FY2021, the District paid six months of rent, or $259,754, and categorized the cost as nonrecurring. Since moving into the new offices the District no longer pays rent and the decrease in expenditure significantly impacts VCAPCD's MOE from previous years. Additionally, the District experienced significant payroll changes impacting its overall budget. In FY2021 VCAPCD approved a general salary increase for all employees. Other changes included senior level employees retiring, with some positions filled by entry level staff at lower starting salaries, and other positions remaining vacant due to the conditions caused by the COVID–19 pandemic. Lastly, many services and supplies were postponed or reduced due to the COVID–19 pandemic. Travel for conferences, trainings, and seminars were cancelled, held virtually, or postponed.

The EPA proposes to find that the request for a reset of VCAPCD's MOE meets the requirements for a non-selective reduction under CAA section 105. The VCAPCD's reduction in rent as a recurrent expenditure, the inability to fill vacant positions created by retirements, and a significant cut back on expenditures caused by the COVID–19 pandemic contributed to the reduction in expenditures.

The EPA proposes that the MOE for VCAPCD's FY2021 CAA section 105 grant be reduced to $5,520,253 to address the non-selective reduction of recurrent expenditures discussed above.

This notice constitutes a request for public comment and an opportunity for public hearing as required by the CAA. All written substantive comments received by August 25, 2022 on this proposal will be considered. The EPA will conduct a public hearing on this proposal only if a written request for such is received by the EPA by August 25, 2022. If no written request for a hearing is received or if the EPA determines that the issues raised are insubstantial, the EPA will proceed to the final action to award the fiscal year 2022 grant to VCAPCD.

Dated: July 20, 2022.

Elizabeth Adams,

Director, Air and Radiation Division, Region IX.

[FR Doc. 2022–15953 Filed 7–25–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–SFUND–2004–0008; FRL–9754–01–OLEM]

Proposed Information Collection Request; Comment Request; Consolidated Superfund Information Collection Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Consolidated Superfund Information Collection Request'' (EPA ICR No. 1487.14, OMB Control No. 2050–0179) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through March 31, 2023. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before September 26, 2022.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–SFUND–2004–0008, online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Yolanda Singer, Office of Superfund Remediation and Technology Innovation, Assessment and Remediation Division, (5204T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–506–1045; email address: *singer.yolanda@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public

docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *https://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This ICR covers the following: (1) the collection of information under 40 CFR part 35, subpart O, which establishes the administrative requirements for cooperative agreements funded under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) for state, federally-recognized Indian tribal governments, and political subdivision response actions; (2) the application of the Hazard Ranking System (HRS) by states as outlined by CERCLA section 105 that amends the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) to include criteria prioritizing releases throughout the United States before undertaking remedial action at uncontrolled hazardous waste sites; and (3) the remedial portion of the Superfund program as specified in CERCLA and the NCP. For cooperative agreements and Superfund state contracts for Superfund response actions, the information is collected from applicants and/or recipients of EPA assistance and is used to make awards, pay recipients, and collect information on how federal funds are being utilized. EPA requires this information to meet its federal stewardship responsibilities. Recipient responses are required to obtain a benefit (federal funds) under 2 CFR part 200, ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards to Non-Federal Entities'' and under 40 CFR part 35, ''State and Local Assistance.'' For the Superfund site evaluation and the Hazard Ranking System, the states will apply the HRS by identifying and classifying those releases or sites that warrant further investigation. The HRS score is crucial since it is the primary mechanism used to determine whether a site is eligible to be included on the National Priorities List (NPL). Only sites on the NPL are eligible for Superfund-financed remedial actions. For the NCP information collection, some community involvement activities covered by this ICR are not required at every site (*e.g.,* Technical Assistance Grants) and depend very much on the community and the nature of the site and cleanup. All community activities seek to involve the public in the cleanup of the sites, gain the input of community members, and include the community's perspective on the potential future reuse of Superfund NPL sites. Community involvement activities can enhance the remedial process and increase community acceptance and the potential for productive and beneficial reuse of the sites.

Form Numbers: 6200–11.

Respondents/affected entities: State, Local or Tribal Governments; U.S. Territories; Communities.

Respondent's obligation to respond: Required to obtain benefits (40 CFR part 35; CERCLA section 105, 40 CFR part 300).

Estimated number of respondents: 13,182 (total).

Frequency of response: Annually.

Total estimated burden: 196,557 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $463,497 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in estimates: There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB. This is because there was no current change in program requirements. EPA expects estimates to likely rise due to an increase in the respondent universe as a result of increased funding from the Infrastructure Investment and Jobs Act of 2021 (Pub. L. 117–58).

Brigid Lowery,

Division Director, Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation.

[FR Doc. 2022–15952 Filed 7–25–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R09–OAR–2022–0401; FRL–9786–01–R9]

Clean Air Act Grant; Santa Barbara County Air Pollution Control District; Opportunity for Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed action; determination with request for comments and notice of opportunity for public hearing.

SUMMARY: The EPA is proposing to determine that the reduction in expenditures of non-Federal funds for the Santa Barbara County Air Pollution Control District (SBCAPCD) in support of its continuing air program under section 105 of the Clean Air Act (CAA) for the calendar year 2021 is a result of non-selective reductions in expenditures. This determination, when final, will permit the SBCAPCD to receive grant funding for fiscal year (FY) 2022 from the EPA, under section 105 of the CAA.

DATES: Comments and/or requests for a public hearing must be received by the EPA at the address stated below on or before August 25, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2022–0401 at *https://www.regulations.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*. The EPA may publish any comment received to its public docket. Please do not submit any information you consider to be Proprietary Business Information (PBI) or 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 (*e.g.,* 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 PBI/CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Angela Latigue, EPA Region IX, Grants & Program Integration Office, Air Division, 75 Hawthorne Street, San Francisco, CA 94105; phone at (415) 947–4170 or email address at *latigue.angela@epa.gov.*

SUPPLEMENTARY INFORMATION: Section 105 of the CAA provides grant funding to air pollution control agencies for the prevention and control of air pollution or implementation of national primary and secondary ambient air quality standards. In accordance with 40 CFR 35.145(a), the Regional Administrator may provide air pollution control agencies up to three-fifths of the approved costs of implementing programs for the prevention and control of air pollution. Air pollution control agencies are required to provide a 40% cost share (also referred to as a match requirement) to receive CAA Section 105 grants. Program activities relevant to the match consist of both recurring and non-recurring (unique, one-time only) expenses. In addition, section 105(c)(1) of the CAA, 42 U.S.C. 7405(c)(1), requires grant recipients to meet a maintenance of effort (MOE).

The MOE provision requires that an eligible agency spend at least the same dollar level of funds as it did in the previous grant year but only for the costs of recurring activities. Specifically, section 105(c)(1) of the CAA, 42 U.S.C. 7405(c)(1), provides that ''No agency shall receive any grant under this section during any fiscal year when its expenditures of non-Federal funds for recurrent expenditures for air pollution control programs will be less than its expenditures were for such programs during the preceding fiscal year.'' However, pursuant to CAA section 105(c)(2), 42 U.S.C. 7405(c)(2), the EPA may still award a grant to an agency not meeting the requirements of section 105(c)(1), ''. . . if the Administrator, after notice and opportunity for public hearing, determines that a reduction in expenditures is attributable to a non-selective reduction in the expenditures in the programs of all Executive branch agencies of the applicable unit of Government.'' These statutory requirements are repeated in the EPA's implementing regulations at 40 CFR 35.140–35.148. The EPA issued a memorandum dated September 30, 2011, entitled ''*Updated Information for Determining a Non-Selective Reduction*'' with additional guidance to recipients on what constitutes a nonselective reduction. In consideration of legislative history, the guidance clarified that a non-selective reduction does not necessarily mean that each executive branch agency needs to be reduced in equal proportion. However, it must be clear to the EPA, from the weight of evidence, that a recipient's CAA-related air program is not being disproportionately impacted or singled out for a reduction.

A section 105 grant recipient must submit a final federal financial report no later than 120 days from the close of its grant period that documents all of its federal and non-federal expenditures for the completed period. The recipient seeking an adjustment to its MOE for that period must provide the rationale and the documentation necessary to enable the EPA to make a determination that a nonselective reduction has occurred. In order to expedite that determination, the recipient must provide details of the budget action and the comparative fiscal impacts on all the jurisdiction's executive branch agencies and the recipient's air program. The recipient needs to identify any executive branch agencies or programs that should be excepted from comparison and explain why. The recipient must provide evidence that the air program is not being singled out for a reduction or being disproportionately reduced. Documentation in key areas is needed including budget data specific to the recipient's air program, and comparative budget data between the recipient's air program, the agency containing the air program, and the other executive branch agencies. The EPA may also request information from the recipient about how impacts on its program operations will affect its ability to meet its CAA obligations and requirements; and documentation which explains the cause of the reduction, such as legislative changes or the issuance of a new executive order.

In fiscal year (FY) 2021, the EPA awarded the SBCAPCD $527,490, which represented approximately 7% of the SBCAPCD budget. In FY2022, the EPA intends to award the SBCAPCD approximately $531,494, which represents approximately 7% of the SBCAPCD budget.

SBCAPCD's final federal financial report for FY2020 indicated that SBCAPCD's MOE level was $7,890,365. The MOE level for FY2021 was reduced to $7,790,365 after formal approval of a non-selective reduction. SBCAPCD's final federal financial report for FY2021 indicates that SBCAPCD's MOE level is at $7,318,050. This level of expenditure is not sufficient to meet the MOE requirements for FY2021 under section 105 because it is not equal to or greater than the MOE for the previous fiscal year.

In order for the SBCAPCD to be eligible to receive its FY2022 CAA section 105 grant, the EPA must make a determination (after notice and an opportunity for a public hearing) that the reduction in expenditures from 2021 to 2022 is attributable to a non-selective reduction in recurrent expenditures in the programs of the SBCAPCD.

The SBCAPCD is a single-purpose air pollution control agency. It is the unit of government for CAA section 105(c)(2) purposes. The main factor for SBCAPCD's MOE shortfall in FY2021 continues to stem from weakened economic conditions caused by the COVID–19 pandemic that resulted in decreases in services and supplies. This budget category was decreased approximately $510,000 from FY19–20 to FY20–21, which is approximately an 11.5% decrease to this recurring expenditure.

The EPA proposes to find that the request for a reset of SBCAPCD's MOE meets the requirements for a non-selective reduction under CAA section 105. The SBCAPCD's MOE reduction resulted from a loss of revenues due to a significant cut back on expenditures caused by the COVID–19 pandemic. Increases in pass-through monies from the California Air Resources Board for multiple state grant projects also impacted the SBCAPCD's overall operating budget. However, such pass-through monies are not considered recurrent expenditures and are not included in calculating MOE.

The EPA proposes that the MOE for SBCAPCD's FY2021 CAA section 105 grant be reduced to $6,700,000 to address the non-selective reduction of expenditures discussed above.

This notice constitutes a request for public comment and an opportunity for public hearing as required by the CAA. All written comments received by August 25, 2022 on this proposal will be considered. The EPA will conduct a public hearing on this proposal only if

a written request for such is received by the EPA by August 25, 2022. If no written request for a hearing is received or if the EPA determines that the issues raised are insubstantial, the EPA will proceed to the final action to award the fiscal year 2022 grant to the SBCAPCD.

Dated: July 20, 2022.

Elizabeth Adams,

Director, Air and Radiation Division, Region IX.

[FR Doc. 2022–15959 Filed 7–25–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

Request for Arbitration Panel

AGENCY: Federal Mediation and Conciliation Service (FMCS).

ACTION: 60-Day notice and request for comments.

SUMMARY: The Federal Mediation and Conciliation Service (FMCS), invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection request, Request for Arbitration Panel, (FMCS Form R–43). This information collection request was previously approved by the Office of Management Budget (OMB) and FMCS is requesting a revision of a currently approved collection. The Request for Arbitration Panel, (FMCS Form R–43), allows FMCS to comply with its statutory obligation pursuant to the statute to make governmental facilities available for voluntary arbitration. To carry out this policy, FMCS have issued regulations which provide for the operation and maintenance of a roster of professional arbitrators. The arbitrators are private citizens, not employees of FMCS, and are paid by the parties for hearing and deciding the issues submitted under a collective bargaining agreement and in other circumstances. The Request for Arbitration Panel (FMCS Form R–43) is used by the parties, labor and management individually or jointly, to request that FMCS furnish a list of arbitrators.

DATES: Comments must be submitted on or before September 26, 2022.

ADDRESSES: You may submit comments, identified by the Request for Arbitration Panel (FMCS Form R–43), through one of the following methods:

- *Email:* Arthur Pearlstein, *apearlstein@fmcs.gov;*
- *Mail:* Arthur Pearlstein, HQ Office of Arbitration, One Independence Square, 250 E St. SW, Washington, DC 20427. Please note that at this time, mail is sometimes delayed. Therefore, we encourage emailed comments.

FOR FURTHER INFORMATION CONTACT: Arthur Pearlstein, 202–606–8103, *apearlstein@fmcs.gov.*

SUPPLEMENTARY INFORMATION: Copies of the agency form are available here. Paper copies are available from the Office of Arbitration Services by emailing Arthur Pearlstein at the email address above. Please ask for the Request for Arbitration Panel (FMCS Form R–43).

I. Information Collection Request

Agency: Federal Mediation and Conciliation Service.

Form Number: OMB No. 3076–0016.

Type of Request: Revision of a currently approved collection.

Affected Entities: Individual who request a list of arbitrators.

Frequency: In most instances, this form is completed once.

Abstract: Title II of the Labor Management Relations Act of 1947, 29 U.S.C. 171(b), provides that ''the settlement of issues between employers and employees through collective bargaining may advance by making available full and adequate governmental facilities for conciliation, mediation, and voluntary arbitration . . .'' 29 U.S.C. 171(b). Pursuant to the statute and 29 CFR part 1404, FMCS has long maintained a roster of qualified, private labor arbitrators to hear disputes arising under collective bargaining agreements and provide fact finding and interest arbitration. The purpose of this information collection is to facilitate the processing of the parties' request for arbitration assistance.

Burden: The number of respondents is approximately 11,000 individuals per year. The time required to complete this form is approximately ten minutes.

II. Request for Comments

FMCS solicits comments to:

i. Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

ii. Enhance the accuracy of the agency's estimates of the burden of the proposed collection of information.

iii. Enhance the quality, utility, and clarity of the information to be collected.

iv. Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic collection technologies or other forms of information technology.

III. The Official Record

The official records are electronic records.

List of Subjects

Labor-Management Relations.

Dated: July 21, 2022.

Anna Davis,

Deputy General Counsel.

[FR Doc. 2022–15964 Filed 7–25–22; 8:45 am]

BILLING CODE 6732–01–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 public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 25, 2022.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Hoosier Heartland State Bancorp Employee Stock Ownership and Savings Plan Trust, Crawfordsville, Indiana;* to become a bank holding company by acquiring additional voting shares of up

to 27.91 percent of Hoosier Heartland State Bancorp, and thereby indirectly acquiring Hoosier Heartland State Bank, both of Crawfordsville, Indiana.

B. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *TransPecos Financial Corp., San Antonio, Texas;* to acquire Luling Bancshares, Inc., and thereby indirectly acquire Citizens State Bank of Luling, both of Luling, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–16018 Filed 7–25–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Reporting and Disclosure Requirements of Community Reinvestment Act (CRA)-Related Agreements (Regulation G) (FR G; OMB No. 7100–0299).

DATES: Comments must be submitted on or before September 26, 2022.

ADDRESSES: You may submit comments, identified by FR G, by any of the following methods:

- *Agency website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number or FR number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M–4775, 2001 C St. NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, 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.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Collection title: Reporting and Disclosure Requirements of Community Reinvestment Act (CRA)-Related Agreements.

Collection identifier: FR G.

OMB control number: 7100–0299.

Frequency: Annually and quarterly.

Respondents: State member banks and their subsidiaries; bank holding companies; savings and loan holding companies; affiliates of bank holding companies and savings and loan holding companies, other than banks, savings associations, and subsidiaries of banks and savings associations; and nongovernmental entities or persons (NGEPs) that enter into covered agreements with any of the aforementioned entities.

Estimated number of respondents: Reporting: insured depository institutions (IDIs) and affiliates—Copy of agreements to agency, 1; List of agreements to agency, 1; Annual report, 1; Filing NGEP annual report, 1; Reporting: NGEP—Copy of agreements to agency, 2, Annual report, 2; Disclosure: IDI and affiliates—Covered agreements to public, 1, Agreements relating to activities of CRA affiliates, 1; and Disclosure: NGEP Covered agreements to public, 2.

Estimated average hours per response: Reporting: IDI and affiliates—Copy of agreements to agency, 1; List of

agreements to agency, 1; Annual report, 4; Filing NGEP annual report, 1; Reporting: NGEP—Copy of agreements to agency, 1, Annual report, 4; Disclosure: IDI and affiliates—Covered agreements to public, 1, Agreements relating to activities of CRA affiliates, 1; and Disclosure: NGEP Covered agreements to public, 1.

Estimated annual burden hours: Reporting: IDI and affiliates—Copy of agreements to agency, 2; List of agreements to agency, 2; Annual report, 4; Filing NGEP annual report, 1; Reporting: NGEP—Copy of agreements to agency, 2, Annual report, 8; Disclosure: IDI and affiliates—Covered agreements to public, 2, Agreements relating to activities of CRA affiliates, 2; and Disclosure: NGEP Covered agreements to public, 2.

General description of report: Regulation G—Disclosure and Reporting of CRA-Related Agreements [1] implements section 711 of the Gramm-Leach-Bliley Act (GLBA),[2] which requires IDIs, affiliates of IDIs, and NGEPs to disclose written agreements entered into in connection with fulfillment of the CRA.[3]

Legal authorization and confidentiality: The disclosure and reporting requirements of Regulation G are authorized pursuant to the Board's authority to prescribe regulations to carry out the purposes of section 711 of GLBA.[4] The FR G disclosure and reporting requirements are mandatory.

The disclosure and reporting requirements of section 711 and Regulation G require relevant parties to disclose covered agreements to the public.[5] However, as explained in the preamble to Regulation G, an entity subject to Regulation G may submit separate public and complete versions of its covered agreements to the Board with a request for confidential treatment for the complete version.[6] As stated in the preamble, the Board would release only the public version unless it received a request under the Freedom of Information Act (FOIA) for the entirety of the CRA-related agreement.[7]

Regulation G states that in responding to a request for a covered agreement from an individual or entity under the public disclosure provisions of section 711, an NGEP, insured depository institution, or affiliate may withhold from the public information that the party believes the relevant supervisory agency could withhold from disclosure under the FOIA.[8] Information contained in covered agreements may be exempt from disclosure under exemption 4 of the FOIA, which protects public commercial or financial information, which is both customarily and actually treated as private by the respondent.[9] Information contained in covered agreements may also be exempt from disclosure under exemption 6 of the FOIA, which protects personnel and medical files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, [10] and under exemption 8 of the FOIA, which protects information contained in ''examination, operating, or condition reports'' obtained in the bank supervisory process.[11]

Board of Governors of the Federal Reserve System, July 20, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–15901 Filed 7–25–22; 8:45 am]

BILLING CODE 6210–01–P

[1] 12 CFR part 207.

[2] Codified at 12 U.S.C. 1831y.

[3] 12 U.S.C. 2901 *et seq.*

[4] 12 U.S.C. 1831y(h)(1).

[5] The Board noted in the preamble to Regulation G that section 711 would require disclosure of some types of information that an agency might normally withhold from disclosure under the FOIA and that the Board would not keep information confidential under the FOIA that a party would be required to disclose under section 711. *Disclosure and Reporting of CRA-Related Agreements,* 66 FR 2052, 2066–2067 (Jan. 10, 2001).

[6] *Id.*

[7] *Id.*

[8] 12 CFR 207.6(b)(2).

[9] 5 U.S.C. 552(b)(4).

[10] 5 U.S.C. 552(b)(6).

[11] 5 U.S.C. 552(b)(8).

FEDERAL TRADE COMMISSION

[File No. P222100]

HISA Enforcement Rule Modification

AGENCY: Federal Trade Commission.

ACTION: Notice of Horseracing Integrity and Safety Authority (HISA) proposed rule modification; request for public comment.

SUMMARY: The Horseracing Integrity and Safety Act of 2020 recognizes a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority, which is charged with developing proposed rules on a variety of subjects. Those proposed rules and proposed rule modifications take effect only if approved by the Federal Trade Commission. The proposed rules and rule modifications must be published in the **Federal Register** for public comment. Thereafter, the Commission has 60 days from the date of publication to approve or disapprove the proposed rule or rule modification. The Authority submitted to the Commission a proposed rule modification on Enforcement on June 5, 2022. The Office of the Secretary of the Commission determined that the proposal complied with the Commission's rule governing such submissions. This document publicizes the Authority's proposed rule modification's text and explanation, and it seeks public comment on whether the Commission should approve or disapprove the proposed rule modification.

DATES: If approved, the HISA proposed rule modification would take effect upon approval, and the Commission must approve or disapprove the proposed rule modification September 26, 2022. Comments must be received on or before August 9, 2022.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Comment Submissions part of the **SUPPLEMENTARY INFORMATION** section below. Write ''HISA Enforcement Rule Modification'' on your comment and file your comment online at *https://www.regulations.gov* under docket number FTC–2022–0044. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Austin King (202–326–3166), Associate General Counsel for Rulemaking, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

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Background

The Horseracing Integrity and Safety Act of 2020 [1] recognizes a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority, which is charged with developing proposed rules on a variety of subjects. Those proposed rules and proposed rule modifications take effect only if approved by the Federal Trade Commission.[2] The proposed rules and rule modifications must be published in the **Federal Register** for public comment.[3] Thereafter, the Commission has 60 days from the date of publication to approve or disapprove the proposed rule or rule modification.[4]

Pursuant to Section 3053(a) of the Horseracing Integrity and Safety Act of 2020 and Commission Rule 1.142, notice is hereby given that, on June 5, 2022, the Horseracing Integrity and Safety Authority (''HISA'' or the ''Authority'') filed with the Federal Trade Commission an Enforcement proposed rule modification and supporting documentation as described in Items I, II, III, and IX below, which Items have been prepared by the Authority. The Office of the Secretary of the Commission determined that the filing complied with the Commission's rule governing such submissions.[5] The Commission publishes this notice to solicit comments on the proposed rule modification from interested persons.

I. Self-Regulatory Organization's Statement of the Background, Purpose of, and Statutory Basis for, the Proposed Rule Modification

a. Background and Purpose

The Horseracing Integrity and Safety Act of 2020 (''Act'') recognizes that the establishment of a national set of uniform standards for racetrack safety and medication control will enhance the safety and integrity of horseracing. The racetrack safety standards are established in the Rule 2000 Series, the ''Racetrack Safety Program,'' filed by the Authority with the Commission on December 6, 2021. The Rule 2000 Series was published in the **Federal Register** on January 5, 2022 [6] and subsequently approved by the Commission by Order dated March 3, 2022.[7] On December 20, 2021, the Authority filed with the Commission the Rule 8000 Series, which establish penalties and adjudicatory procedures for the enforcement of rules promulgated by the Authority. The Rule 8000 Series was published in the **Federal Register** January 26, 2022 [8] and approved by the Commission by Order dated March 25, 2022.[9]

In its Order, the Commission directed the Authority to file modifications to three provisions in the Rule Series 8000, stating as follows: ''The Commission directs the Authority (1) to not impose the proposed sanction in Rule 8200(b)(6) on a covered person until such time as the Authority has proposed, and the Commission has approved, a rule modification that is more narrowly tailored; (2) to file with the Commission, by July 1, 2022, a supplemental proposed rule modification explicitly stating guidelines for confidentiality and public reporting at the different stages of the processes outlined in the Enforcement rule; and (3) to file with the Commission, by July 1, 2022, a supplemental proposed rule modification in which the Authority further defines the meaning of 'object' and 'device' within proposed Rule 8400(a)(2)'s list of items eligible for seizure and provides a process for the return of seized property if no violation is found.'' [10]

The Authority therefore proposes the rule changes described in this Notice in order to fulfill the Commission's directives. In addition, the Authority on its own initiative proposes to amend the Rule 8000 Series and to supplement it with additional provisions. Some of these amendments and supplements have been prompted by comments and suggestions received from interested members of the horseracing industry since the rules were filed on December 20, 2021.

The violations, adjudications, and search procedures in the Rule 8000 Series are tailored to the unique aspects of horseracing in that violations of the rules of horseracing do arise in the sport and must be penalized. Violations must be effectively penalized to deter future violations and to ensure that horseracing is conducted in a fair and transparent manner that ensures public confidence in the integrity of the sport. Various specific violations are established in Rule 8100, and the schedule of sanctions set forth in Rule 8200 provides the specific penalties that are the consequence of committing a rule violation. The schedule is tailored to the unique aspects of horseracing in that it imposes revocations, suspensions, substantial fines, exclusions from racetrack grounds, and other penalties that are commonly imposed upon licensed participants in horseracing.

Before a penalty is imposed, persons alleged to have committed violations are entitled to a fair hearing at which they are afforded an opportunity to present evidence in defense of a charged violation. While a full process hearing is available on appeal of cases to the Commission pursuant to 15 U.S.C. 3058(b), hearing processes are also necessary before various bodies of the Authority to make sure that any penalties imposed upon Covered Persons are adjudicated carefully and fairly. This ensures that violations are consistently and fairly penalized. The provisions set forth in Rule 8300 establish the rules and parameters of the various hearing processes. These provisions also provide for appeals to the Board of the Authority to review any decisions rendered against a Covered Person who is charged with a violation. The various hearing procedures are keyed to the unique organizational structure of the Authority. Rules 8200(d) and 8360 also establish procedures for notices of violations and hearings to adjudicate the denial, suspension, or revocation of racetrack accreditation in those instances in which racetracks are alleged to have committed violations of the Racetrack Safety rules. Racetrack safety is of course unique to horseracing and is essential to ensure that horseracing is conducted safely and in a fair and transparent manner.

The successful prosecution of violations requires the investigation of all the circumstances surrounding an alleged violation. Central to any investigation is the power to gain access to the books, records, and certain premises of persons believed to have committed a violation; to subpoena witnesses; and to take testimony under

[1] 15 U.S.C. 3051 through 3060.

[2] 15 U.S.C. 3053(b)(2).

[3] 15 U.S.C. 3053(b)(1).

[4] 15 U.S.C. 3053(c)(1).

[5] 16 CFR 1.140 through 1.144; *see also* Fed. Trade Comm'n, Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act, 86 FR 54819 (Oct. 5, 2021), *https://www.federalregister.gov/documents/2021/10/05/2021-21306/procedures-for-submission-of-rules-under-the-horseracing-integrity-and-safety-act.*

[6] *See* Fed. Trade Comm'n, Notice of HISA Racetrack Safety Proposed Rule (''Notice''), 87 FR 435 (Jan. 5, 2022), *https://www.federalregister.gov/documents/2022/01/05/2021-28513/hisa-racetrack-safety.*

[7] *See* Fed. Trade Comm'n, Order Approving the Racetrack Safety Rule Proposed by the Horseracing Integrity & Safety Auth. at 1, ____F.T.C.____ (Mar. 3, 2022), *https://www.ftc.gov/system/files/ftc_gov/pdf/order_re_racetrack_safety_2022-3-3_for_publication.pdf.*

[8] *See* Fed. Trade Comm'n, *HISA Enforcement Rule,* 87 FR 4,023, 4,028 (Jan. 26, 2022), *https://www.federalregister.gov/documents/2022/01/26/2022-01663/hisa-enforcement-rule.*

[9] *See* Fed. Trade Comm'n, Order Approving the Enforcement Rule Proposed by the Horseracing Integrity & Safety Auth., at 1, ____F.T.C.____ (Mar. 25, 2022) (''Enforcement Rule Order''), *https://perma.cc/H9SJ-F9WA.*

[10] *Id.* at 35–36.

oath of any person with knowledge of the circumstances regarding a violation. Rule 8400 specifically confers these powers upon the Authority and penalizes any obstruction or failure to comply with the investigatory powers set forth in the section.

The proposed rule modification is described in detail in Item II of this Notice. Various rules pertaining to horseracing and equestrian sports that were consulted in the development of this proposed rule modification are available as Exhibit A at the docket at *https://www.regulations.gov.* In conformity with 15 U.S.C. 3057(d)(2) of the Act, the various modifications described take into account the unique aspects of horseracing, are designed to ensure fair and transparent horseraces, and will serve to deter safety and performance violations. Anti-doping and medication control rule violations will be established in detail in proposed rules to be filed later this year.

On May 13, 2022, HISA representatives shared a draft of the proposed rule modification with a number of interested stakeholders for input. Those interested stakeholders included: Racing Officials Accreditation Program; Racing Medication and Testing Consortium (Scientific Advisory Committee); Water Hay Oats Alliance; National Thoroughbred Racing Association; The Jockey Club; The Jockeys' Guild; Thoroughbred Racing Association; Arapahoe Park; Grants Pass Downs; Arizona Downs; Colonial Downs; Thoroughbred Owners of California; California Horse Racing Board; National Horsemen's Benevolent and Protective Association; Thoroughbred Horsemen's Association Mid-Atlantic Safety Coalition; Thoroughbred Owners and Breeders Association; Kentucky Thoroughbred Association; American Association of Equine Practitioners; American Veterinary Medical Association; Delaware Racing Commission; New York Racing Association, Stronach Racing Group (5 thoroughbred racetracks); Churchill Downs (6 thoroughbred racetracks); Keeneland; and Del Mar. On May 13, 2022, the rule modification proposal was made available to the public for review and comment on the HISA website at *https://www.hisausregs.org.* Several comments were received from various stakeholders, which are outlined in Item III of this Notice. Available at the docket on *https://www.regulations.gov* as Exhibit B are copies of all pre-submission comments received concerning the proposed rule modification.

With the review, input, and ultimate approval of the Authority's Board of Directors, the proposed rule modification to the Rule 8000 Series modifies and enhances the penalties and adjudication procedures for the enforcement of rules promulgated by the Authority.

b. Statutory Basis

The Horseracing Integrity and Safety Act of 2020, 15 U.S.C. 3051 through 3060.

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Enforcement Proposed Rule Modification and Discussion of Alternatives

Rule 8200(b)(6), as originally filed with the Commission on December 20, 2021, established a penalty that operated to ''bar a Covered Person from associating with all Covered Persons concerning any matter under the jurisdiction of the Commission and the Authority during the period of a suspension.'' The Commission directed the Authority to ''not impose this sanction on a covered person until such time as the Authority has proposed, and the Commission has approved, a rule modification that is more narrowly tailored.'' [11] In response to this directive, the Authority considered alternative sanctions currently in place in various state racing jurisdictions. The Authority now proposes to replace the penalty language quoted above with a different sanction in Rule 8200(b)(6), which will authorize the Authority to ''deny a Covered Person or a Covered Horse access to any location under the jurisdiction of the Authority during the period of a suspension.'' With this revision, Rule 8200(b)(6) will no longer place broad restraints upon a Covered Person's association with other Covered Persons but instead will prohibit a Covered Person from entering upon grounds under the jurisdiction of the Authority. The provision will accomplish the same basic end, which is to restrict Covered Persons from direct involvement with racing activities on grounds under the jurisdiction of the Authority during the period of a suspension. The restriction makes the suspension meaningful and deters future violations, thus furthering the goal of ensuring fair and transparent horseraces in a manner consistent with 15 U.S.C. 3057(d). By operating to exclude a Covered Person from horseracing grounds, the provision is tailored to the unique aspects of horseracing and is similar to provisions in the regulations of Kentucky and Minnesota, as well as the Model Rules of the Association of Racing Commissioners International (''ARCI'').

In its Order, the Commission also directed the Authority ''to file with the Commission by July 1, 2022 a supplemental proposed rule modification explicitly stating guidelines for confidentiality and public reporting at the different stages of the processes outlined in the Enforcement rule.'' [12] The Authority proposes to amend the Rule Series 8000 to include a new Rule 8380, entitled ''Guidelines for Confidentiality and Public Reporting.'' The rule draws upon a similar provision in the rules of the International Equestrian Federation (''FEI'') that governs public disclosure and confidentiality in the realm of equestrian sports.[13] Provisions of this kind in horseracing regulations are typically spare and lacking in detail, but the FEI Rules provide a sound framework for the development of the Authority's proposed rule.

The rule serves the interest of providing greater transparency to the public concerning the adjudication of rule violations. In many cases involving the violation of medication rules in particular, little is known by the public of the details of an alleged violation beyond rumor and speculation. This is because, in many racing jurisdictions, regulators—particularly at the initial level of adjudication before the state stewards—are prohibited from disclosing information concerning the alleged violation. The proposed Rule 8380 will loosen these restrictions and require the Authority to disclose basic facts about the alleged violation, including ''(1) the identity of the Covered Person who is the subject of the alleged violation, (2) the identity of any applicable Covered Horse, and (3) the rule violated and, where appropriate, the basis of the asserted violation.'' The rule also permits the Authority to comment on any information disclosed by the Covered Person charged with the alleged violation. In some instances, persons charged have made public statements concerning contested facts, and regulators should have the ability to respond to inaccurate comments if they cast unfounded doubt upon the legitimacy of the disciplinary process or of horseracing in general.

In addition, Rule 8380 also contains provisions that permit the Authority to refrain from any public disclosure in situations that would compromise an

[11] *Id.* at 15.

[12] *Id.* at 29.

[13] *See* FEI Equine Anti-Doping and Controlled Medication Regulations, Article 13.

ongoing investigation or in circumstances in which the Covered Person charged with a violation is a minor. Conversely, the Authority is permitted in the interest of public safety to make any disclosure that concerns a violation or circumstance that poses a serious and imminent risk of harm to Covered Persons, Covered Horses, or the public. Rule 8380 further provides for the disclosure of detailed information within 20 days of the imposition of a sanction, the resolution of a matter between the parties, or the dismissal of the action.

By providing the public with information concerning alleged violations, the public disclosure rule works toward the goal of ensuring fair and transparent horseraces in a manner consistent with 15 U.S.C. 3057(d). It takes into account the unique aspects of the adjudication of alleged violations of the rules of horseracing, and by strengthening the system of adjudication it helps to deter future violations while at the same time enhancing public confidence in the sport.

In its Order, the Commission directed the Authority ''to submit to the Commission a supplemental proposed rule modification by July 1, 2022, in which the Authority further defines the meaning of 'object' and 'device' within proposed Rule 8400(a)(2)'s list of items eligible for seizure ('medication, drug, substance, paraphernalia, object, or device') and that provides a process for the return of seized property if no violation is found.'' [14]

It is difficult to define ''object'' or ''device'' with precision, and other racing rules consulted by the Authority do not provide definitions for these or similar terms in a seizure context. Nevertheless, the proposed modification amends the language of the Rule as originally filed to specify that the Authority may seize ''any object or device reasonably believed to have been used in furtherance of the violation or suspected violation.'' Objects that might be used in furtherance of prohibited activity include intravenous tubing, oral dosing syringes, needles, nasal gastric tubes, various types of container bags and vials, and many other items. The language is broad enough to include devices such as computers and phones if there is reason to believe that these devices have been used in furtherance of a violation. In doping and medication-violation cases in particular, it is often found that information concerning medications and drugs administered to horses are stored on computers and phones. Rather than try to construct definitions of ''object'' or ''device'' that will likely be vague and fail to include certain items while including others in an overly expansive manner, the Authority has proposed language that closely ties the terms ''object'' and ''device'' to the violation being investigated; seizure is justified only if the object or device is reasonably believed to have been used in furtherance of the violation or suspected violation.

Additionally, and pursuant to the directive of the Commission, the proposed rule modification includes a new provision in Rule 8400(a)(3) that requires the Authority to return seized property upon the final resolution of a violation, so long as the possession of the property is not specifically prohibited by the Act or the rules of the Authority. Many racing jurisdictions return property as a matter of course, though not specifically required to do so; the Authority's rule requires property to be returned unless specifically prohibited.

The changes to the language referencing the words ''object'' and ''device,'' as directed by the Commission, take into account the unique aspects of horseracing violation investigations, especially the necessities of seizure in medication-violation cases. By providing effective measures to seize evidence, the modification enhances the investigation and successful adjudication of violations, thus deterring future violations in a manner consistent with 15 U.S.C. 3057(d). An effective enforcement system builds public confidence in the sport by ensuring that horseracing is conducted in a fair and transparent manner. The return policy is adopted as a matter of fairness to Covered Persons whose property has been seized; property that is not specifically prohibited under the Authority's rules shall be returned upon the final resolution of a violation.

In addition to the amendments directed by the Commission, the Authority has also proposed several modifications on its own initiative. And, in some instances, rule changes have been prompted in response to comments previously received during the formal comment period after the filing of the Rule 8000 Series with the Commission on December 20, 2021.

Rule 8400(a)(2) gives the Authority the power to ''seize any medication, drug, substance, paraphernalia, object, or device in violation or suspected violation of any provision of 15 U.S.C. Chapter 57A or the regulations of the Authority.'' As noted in the Commission's Order, some commenters to the Rule 8000 Series expressed concerns that the seizure provisions were overbroad, though the referenced language in the Rule 8000 Series as originally filed was approved by the Commission.[15] The language of the rule tracked the statutory language at 15 U.S.C. 3054(c)(1), which states in pertinent part that the Authority ''shall develop uniform procedures and rules authorizing—(i) access to offices, racetrack facilities, other places of business, books, records, and personal property of covered persons that are used in the care, treatment, training, and racing of covered horses.'' It should also be noted that statutes in other state racing jurisdictions are similarly broad (such as Kentucky). The Commission addressed this matter in detail in the Order approving the Enforcement rules, noting that the commenters' objections are really with the Act itself.[16] Nevertheless, to allay the concerns expressed, the Authority has filed a proposed rule modification that restricts the scope of Rule 8400(1)(a). Specifically, the new language authorizes the Commission, the Authority, or their designees to have free access to books, records, offices, racetrack facilities, and other places of business of both Covered Persons and any person who owns a Covered Horse or performs services on a Covered Horse, but the language requires that the items and locations subject to access must relate to the care, treatment, training, and racing of Covered Horses. This provision is included to clarify that items and locations unrelated to horseracing may not be accessed by the Authority.

Rule 8100(g) is modified to include as a violation the ''failure of a Responsible Person to register a Covered Horse.'' After the Rule 8000 Series was filed on December 20, 2021, the Authority developed and filed, on April 25, 2022, the Rule 9000 Series, ''Registration of Covered Persons and Covered Horses.'' The Commission approved the Registration rule by Order dated June 29, 2022.[17] Rule 9000(i) requires Responsible Persons to ensure that Covered Horses are registered with the Authority. A penalty is therefore added to Rule 8100(g) to authorize the imposition of sanctions for failure to do so.

In Rule 8200(b), ''Imposition of Sanctions,'' the Authority proposes to

[14] Enforcement Rule Order at 34–35.

[15] *See id.* at 30–35.

[16] *See id.* at 34.

[17] *See* Fed. Trade Comm'n, Order Approving Registration Rule Proposed by Horseracing Integrity & Safety Auth., at 1 (June 29, 2022), *https://www.ftc.gov/system/files/ftc_gov/pdf/P222100CommissionOrderRegistrationRuleFinal.pdf.*

modify this provision to specify that any penalties imposed under that Rule shall be ''in proportion to the nature, chronicity, and severity of the violation.'' This language provides a rubric or standard to guide discretion in the imposition of penalties. In the same paragraph, a scrivener's error is corrected to refer to the Rule 8000 Series to make clear that sanctions are imposed after hearings conducted under the rules of both the Rule 7000 and 8000 Series. Additionally, the Authority proposes to modify Rule 8200(b)(2)(ii) concerning the fines that may be imposed for second violations of Authority rules. Under the Rule as originally filed, the fine was established at $50,000.00 to $100,000.00; the Rule will be modified to state that a fine may be imposed in an amount ''up to $100,000.00.'' This modification will give the Authority greater flexibility in assessing a fine in proportion to the nature, chronicity, and severity of the violation.

Rule 8200(d) is amended to recognize that ''one or more stewards'' may issue a Notice of Suspected or Actual Violation, in addition to the Authority and the Racetrack Safety Committee. In addition, the Authority proposes to amend Rule 8200(d)(iii) to permit the Authority to consider ''any other relevant factor'' in establishing the time period allowed for a Covered Person to respond to a Notice of Suspected or Actual Violation. This catch-all provision is added to allow consideration of all relevant factors pertaining to the response time, in addition to the seriousness of the violation and the imminence of risk to Covered Persons, Covered Horses, Covered Horseraces or the public.

The Authority is proposing modifications to several provisions in Rule 8300 to elaborate upon the procedures to be followed by track-level stewards in adjudicating penalties. The provisions to be amended are Rule 8320(a), Rule 8320(b)(3), and Rule 8330(c), and the language of the amendment is similar in each rule. The amendment states more explicitly than the original language in the rules that the stewards shall adjudicate all alleged violations of Rules 2271(b) or 2272 relating to the use of Shock Wave Therapy, violations of Rule 2280 relating to the use of the riding crop, and violations of Rule 2273 relating to the use of other electrical or mechanical devices. The amendment also makes clear that the stewards shall utilize the hearing procedures of the state jurisdiction in which a violation is alleged to have occurred.

The amendment further addresses the broader issue of whether a state racing commission has entered into an agreement under which the state stewards serve in an adjudicatory capacity under the Rule 8000 Series and enforce the Rule 2200 Series. In those states in which the state racing commission has not entered into an agreement with the Authority, the amendment provides that stewards appointed by the Authority to enforce the Rule 2200 Series shall adjudicate these cases. Since the burden of enforcing these rules will not be heavy in many jurisdictions, only one steward may be necessary to adjudicate violations under the Rule 2200 Series. If this is the case in a particular jurisdiction, the amendment makes clear that one steward may adjudicate these violations regardless of whether the state jurisdiction's rules require two or three stewards to rule on violations. In addition, the amendment to Rule 8320(a) further provides that all testimony at a stewards' hearing shall be given under oath, and a record of the hearing shall be kept by use of an audio recorder, video recording, or court reporter's transcript. While this is already routinely done in many jurisdictions, the new language makes the requirement explicit.

The Authority proposes to amend Rule 8320(b)(1) and Rule 8330(a) in an identical manner to specify that when a case is referred to the National Stewards Panel by the Racetrack Safety Committee or the Board, ''one or more members'' of the Panel may be designated to adjudicate the case. This amendment is included to bring Rule 8330 in conformity with Rules 3000 and 7000 Series, which will establish and set forth the procedures applicable to the National Stewards Panel. These rules are under development and will be filed with the Commission prior to January 1, 2023.

Several amendments are proposed to modify Rule 8340, ''Initial Hearings Conducted Before the Racetrack Safety Committee or the Board of the Authority.'' Rule 8340(3) as previously filed states that ''[a]ll testimony in proceedings before the Board or the Racetrack Safety Committee shall be given under oath;'' that paragraph is amended to further state that ''a record of the proceedings shall be kept in stenographic or recorded form.'' Rule 8340(h) is amended to make clear that a party to initial hearings before the Board or the Racetrack Safety Committee is entitled to be represented by counsel at the party's expense.

Additional rules are proposed for inclusion in Rule 8340 that permit the Board and the Racetrack Safety Committee to appoint a presiding officer to assist in the conduct of hearings. Rule 8340(i) specifies that the presiding officer may be assigned to exercise various powers similar to those that are performed by administrative law judges in contested proceedings at the state and federal level. These powers are set forth with specificity in the proposed rule and generally serve to ensure the orderly conduct of the presentation of evidence and witnesses and to regulate the conduct of parties and their attorneys. The Authority consulted and closely followed similar provisions in the ''Hearing Rules and Procedures'' of the New York Racing Association in developing these rules.

The presiding officer may also be directed by the Board and the Racetrack Safety Committee under Rule 8340(j) to prepare a hearing report with a recommended penalty, if applicable, and the parties may be required to file briefs for consideration by the hearing officer in preparing the hearing report. The rule states that once the hearing report has been received by the Racetrack Safety Committee or the Board, these bodies may adopt, modify, or reject any or all the hearing report, including any recommended penalty. These rules parallel similar concepts in Kentucky's statutory scheme concerning the conduct of administrative hearings by an administrative law judge. Rule 8350, ''Appeal to the Board,'' is amended in paragraphs (h) and (i) to permit the Board in appeal proceedings to appoint a hearing officer under the same rules set forth in Rule 8340 concerning the conduct of initial hearings and the preparation of a hearing report. Additionally, Rule 8350(e) is amended to specify that the Board has the discretion to decide an appeal solely upon written submissions or in the alternative to conduct a hearing upon the issues raised by the appeal. In the same rule, the word ''heard'' is replaced with the word ''reviewed'' to conform to the change. Rule 8350(c) is modified to provide that a stay may be issued on appeal not only by the Board but also ''by any official or body of the Authority to whom the Board delegates the authority to review requests for stay.''

Rule 8360, ''Accreditation Procedures,'' is amended in several places to include the words ''suspended'' or ''suspension,'' to conform to Rule 2116, ''Suspension and Revocation of Accreditation,'' which authorizes suspension as a penalty. Rule 8360(f)(1) is revised to refer more precisely to the ''Board'' in the context of the rule, rather than the ''Authority.'' The word ''an'' is added to correct a scrivener's error in Rule 8360(f)(2). A

short provision, Rule 8011, is added to specify that time is calculated under the Rule 8000 Series in calendar days and that, if the last day of a specified period of time falls on a Saturday, Sunday, or holiday, the last day shall be considered to be the next working day following the Saturday, Sunday, or holiday.

III. Self-Regulatory Organization's Summary of Comments Received Pre-Submission and Its Responses to Those Comments

As encouraged by the Commission's procedural rule, the Authority, before finalizing this submission to the Commission, made a draft of the Enforcement proposed rule modification available to the public for review and comment on the HISA website, *https://www.hisausregs.org/.* Comments on the proposed rule modification were received from five individuals and groups in the horseracing industry: The Jockey Club, The Jockeys' Guild, Racing Officials Accreditation Program (''ROAP''), Colonial Downs Racetrack, and the American Association of Equine Practitioners (''AAEP'').

Two of the commenters, Colonial Downs Racetrack and AAEP, stated that they had reviewed the proposed rule modification and had no suggested changes to offer. The three other commenters, The Jockey Club, The Jockeys' Guild, and ROAP, did not question or critique the proposed rule modifications as a whole but instead offered constructive suggestions to fine-tune various provisions in the initial drafts of the proposed rule modification. The Authority adopted a number of these suggested changes into the proposed rule modification as it developed into its final form.

ROAP suggested that a lengthy sentence in an initial draft of Rule 8320(a) concerning adjudication by the stewards be broken into two sentences for clarity. The Authority amended the sentence according to the suggestion, with some additional modifications. The Jockeys' Guild suggested that a short provision be added to Rule 8200(d), Notice of Suspected or Actual Violation, to clarify that the Authority may make a finding of no violation after review of a Covered Person's response to a Notice. Language was added in conformity with the suggestion.

The Jockey Club suggested that Rule 8340(c)(3), which requires notice to be provided in advance of a hearing before the Board or the Racetrack Safety Committee, be amended to replace ''alleged violation'' with ''rule or rules allegedly violated.'' This suggestion is well taken and is included in the proposed rule modification for clarity.

The Authority also implemented a suggestion from The Jockey Club that language be added to permit hearings by the Board and the Racetrack Safety Committee under Rules 8340(a) and (b) and Rule 8350 to be conducted both in-person and through the use of audio-visual teleconferencing. This language was included in the draft, and the Authority added language to permit the use of telephone audio systems as well.

The Jockey Club also helpfully suggested that, if a hearing report is created, the parties should be permitted to file exceptions to the reports ''as a matter of right.'' The draft language of Rule 8340(j) was therefore amended to make clear that exceptions may be filed by the parties to a hearing report.

The Authority declined to make some of the changes suggested by the commenters. Two of the suggestions were of more significance than the rest. The Jockey Club suggested that the seven-day deadline for a Covered Person's response to a Notice of Suspected or Actual Violation in Rule 8200(d)(1)(iii) be extended to twenty or thirty days. The Authority declined to make this change because some violations may present a hazard to racing participants and the public, and a rapid resolution of the matter is necessary. Nevertheless, the Rule provides for a longer response time ''as deemed appropriate and specified in the notice,'' based on the seriousness of the violation and the imminence of risk to Covered Persons, Covered Horses, and the public. In cases where those concerns are not present, it is anticipated that a longer response time will be specified in the notice as appropriate to the case.

The Jockeys' Guild suggested that the term ''good cause'' be further defined in Rule 8350, which provides that a penalty may be stayed upon good cause shown. The Authority considered this change but opted to let the rule stand as written. This term is frequently employed without further definition in many areas of the law, and it is difficult to enumerate all of the factual circumstances that may qualify as a showing of ''good cause.''

The remaining suggestions that the Authority declined to adopt involved minor revisions to various rules that the Authority believed were unnecessary to effectuate the intention of the rules. Some of the comments received posed questions about the application of a provision, rather than suggesting specific changes. In such instances no change was made, but the Authority is working diligently to educate and inform the racing community about the new rules to be implemented by the Authority.

All of the changes proposed in the proposed rule modification are intended to enhance the Rule 8000 Series in a manner consistent with 15 U.S.C. 3057(d). An effective enforcement system builds public confidence in the sport by ensuring that Covered Horseraces are conducted in a fair and transparent manner. The proposed rules are carefully tailored to the unique character of horseracing and to the organizational structure of the Authority. Covered Persons will benefit from the effective enforcement of the rules, the standards of integrity in racing that the rules establish, and the deterrence of violations. The safety and well-being of Covered Horses, always a primary concern to the Authority, will be safeguarded by the elaborate Rule 2000 Series Racetrack Safety rules promulgated by the Authority, and by the Rule 8000 Series that ensures that the Racetrack Safety rules are effectively enforced.

IV. Legal Authority

This rule modification is proposed by the Authority for approval or disapproval by the Commission under 15 U.S.C. 3053(c)(1).

V. Effective Date

If approved by the Commission, this proposed rule modification will take effect immediately.

VI. Request for Comments

Members of the public are invited to comment on the Authority's proposed rule modification. The Commission requests that factual data on which the comments are based be submitted with the comments. The supporting documentation referred to in the Authority's filing, as well as the written comments it received before submitting the proposed rule modification to the Commission, are available for public inspection at *https://www.regulations.gov* under docket number FTC–2022–0044.

The Commission seeks comments that address the decisional criteria provided by the Act. The Act gives the Commission two criteria against which to measure proposed rules and rule modifications: ''The Commission shall approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with—(A) this chapter; and (B) applicable rules approved by the Commission.'' [18] In other words, the Commission will evaluate the proposed

[18] 15 U.S.C. 3053(c)(2).

rule modification for its consistency with the specific requirements, factors, standards, or considerations in the text of the Act as well as the Commission's procedural rule.

Although the Commission must approve the proposed rule modification if the Commission finds that the proposed rule modification is consistent with the Act and the Commission's procedural rule, the Commission may consider broader questions about the health and safety of horses or the integrity of horseraces and wagering on horseraces in another context: ''The Commission may adopt an interim final rule, to take effect immediately, . . . if the Commission finds that such a rule is necessary to protect—(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces.'' [19] The Commission may exercise its power to issue an interim final rule on its own initiative or in response to a petition from a member from the public. If members of the public wish to provide comments to the Commission that bear on protecting the health and safety of horses or the integrity of horseraces and wagering on horseraces but do not discuss whether the Authority's Enforcement proposed rule modification is consistent with the Act or the applicable rules, they should not submit a comment here. Instead, they are encouraged to submit a petition requesting that the Commission issue an interim final rule addressing the subject of interest. The petition must meet all the criteria established in the Rules of Practice (Part 1, Subpart D); [20] if it does, the petition will be published in the **Federal Register** for public comment. In particular, the petition for an interim final rule must ''identify the problem the requested action is intended to address and explain why the requested action is necessary to address the problem.'' [21] As relevant here, the petition should provide sufficient information for the public to comment on, and for the Commission to find, that the requested interim final rule is ''necessary to protect—(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces.'' [22]

VII. Comment Submissions

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 9, 2022. Write ''HISA Enforcement Rule Modification'' on your comment. Your comment—including your name and your State—will be placed on the public record of this proceeding, including, to the extent practicable, on the website *https://www.regulations.gov*.

Because of the public health emergency in response to the COVID–19 outbreak and the Commission's heightened security screening, postal mail addressed to the Commission will be subject to delay. The Commission strongly encourages that comments be submitted online through the *https://www.regulations.gov* website. To ensure that the Commission considers online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write ''HISA Enforcement Rule Modification'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580.

Because your comment will be placed on the public record, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not contain sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other State identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential''—as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *https://www.regulations.gov*—as legally required by FTC Rule 4.9(b), 16 CFR 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments it receives on or before August 9, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/siteinformation/privacypolicy*.

VIII. Communications by Outside Parties to the Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding, from any outside party to any Commissioner or Commissioner's advisor, will be placed on the public record. *See* 16 CFR 1.26(b)(5).

IX. Self-Regulatory Organization's Proposed Rule Language

The following language reflects the Enforcement rule with the proposed modifications incorporated. A redline version that shows every way in which the previously approved Enforcement rule would be modified by the proposed rule modification is available as Exhibit C on the docket at *https://www.regulations.gov*.

8000. Violations, Sanctions, Hearing Procedures, and Investigatory Powers

8011. Calculation of Time

In calculating any period of time prescribed in the Rule 8000 Series, time shall be calculated in calendar days. If the last day of a specified period of time falls on a Saturday, Sunday, or holiday, then the last day of the period shall be considered to be the next working day immediately following the Saturday, Sunday, or holiday.

[19] 15 U.S.C. 3053(e).

[20] 16 CFR 1.31; *see* Fed. Trade Comm'n, Procedures for Responding to Petitions for Rulemaking, 86 FR 59851 (Oct. 29, 2021).

[21] 16 CFR 1.31(b)(3).

[22] 15 U.S.C. 3053(e).

8100. Violations

Violations under this Rule shall include:

(a) Failure to cooperate with the Authority or an agent of the Authority during any investigation;

(b) Failure to respond truthfully, to the best of a Covered Person's knowledge, to a question of the Authority or an agent of the Authority with respect to any matter under the jurisdiction of the Authority;

(c) Tampering or attempted tampering with the application of the safety, performance, or anti-doping and medication control rules or process adopted by the Authority, including:

(1) Intentional interference, or an attempt to interfere, with an official or agent of the Authority;

(2) Procurement or the provision of knowingly false information to the Authority or agent of the Authority; and

(3) The intimidation of, or an attempt to intimidate, a potential witness;

(d) Assisting, encouraging, aiding, abetting, conspiring, covering up, or any other type of intentional complicity involving a racetrack safety violation, or the violation of a period of suspension or ineligibility;

(e) Threatening or seeking to intimidate a person with the intent of discouraging the person from the good faith reporting to the Authority, an agent of the Authority, or the Commission, of information that relates to:

(1) A suspected or alleged violation of a rule in the Rule 2200 Series; or

(2) A suspected or alleged noncompliance with a rule in the Rule 2200 Series;

(f) Failure to comply with a written order or ruling of the Authority or an agent of the Authority pertaining to a racing matter or investigation;

(g) Failure to register with the Authority, failure of a Responsible Person to register a Covered Horse, making a knowingly false statement or omission of information in an application for registration with the Authority, or failure to advise the Authority of material changes in the application information as required under any provision in Authority regulations;

(h) Perpetrating or attempting to perpetrate a fraud or misrepresentation in connection with the care or racing of a Covered Horse;

(i) Failure to remit fees as required under 15 U.S.C. 3052(f)(3); and

(j) Failure by a Racetrack to collect equitable allocation amounts among Covered Persons in conformity with the funding provisions of 15 U.S.C. 3052(f)(3) and any rules pertaining thereto.

8200. Schedule of Sanctions for Violations; Consent Decrees; Notice of Suspected or Actual Violation

(a) Application. This Schedule shall apply to any violation of, or failure to comply with, the Act or regulations promulgated by the Authority by a Covered Person, except for:

(1) Anti-doping and medication control rule violations as established in the Rule 3000 Series; and

(2) State laws or regulations not pre-empted by 15 U.S.C. 3054(b).

(b) Imposition of Sanction. The Authority, the Racetrack Safety Committee, the stewards, any steward or body of stewards selected from the National Stewards Panel, or an Arbitral Body, after any hearing required to be conducted in accordance with the Rule 7000 Series or Rule 8000 Series and upon finding a violation or failure to comply with the regulations of the Authority with the exceptions identified in paragraph (a), may impose one or more of the following sanctions on a Covered Person for each violation of the rules of the Authority, in proportion to the nature, chronicity, and severity of the violation:

(1) For a violation of Rule 2271(b) or 2272 relating to the use of Shock Wave Therapy, a violation of Rule 2273 relating to the use of other electrical or mechanical devices, or a violation of Rule 2280 relating to the use of the riding crop, impose the penalties set forth in Rules 2272, 2274, 2282, and 2283, in addition to any penalty set forth in Rule 8200(b)(2) through (12);

(2) Impose a fine upon a Covered Person in the following amounts:

(i) Up to $50,000.00 for a first violation, or

(ii) Up to $100,000.00 for a second violation of the same or similar nature to a prior violation, or any violation that due to its nature, chronicity, or severity poses an actual or potential threat of harm to the safety, health, and welfare of Covered Persons, Covered Horses, or the integrity of Covered Horseraces;

(3) Deny or suspend the registration of a Covered Person for a definite period, probationary period, or a period contingent on the performance of a particular act;

(4) Revoke the registration of a Covered Person subject to reapplication at a specified date;

(5) Impose a lifetime ban from registration with the Authority;

(6) Deny a Covered Person or a Covered Horse access to any location under the jurisdiction of the Authority during the period of a suspension;

(7) Impose a temporary or permanent cease and desist order against a Covered Person;

(8) Require a Covered Person as a condition of participation in horseracing to take any remedial or other action that is consistent with the safety, welfare, and integrity of Covered Horses, Covered Persons, and Covered Horseraces;

(9) Deny or require the forfeiture of purse money, disqualify a horse, or make changes to the order of finish in Covered Races as consistent with the safety, welfare, and integrity of Covered Horses, Covered Persons, and Covered Horseraces;

(10) Censure a Covered Person;

(11) Prohibit a Racetrack from conducting any Covered Horserace; or

(12) Impose any other sanction as a condition of participation in horseracing as deemed appropriate by the Authority in keeping with the seriousness of the violation and the facts of the case, and that is consistent with the safety, welfare, and integrity of Covered Horses, Covered Persons, and Covered Horseraces.

(c) Consent Decrees. The Authority shall have the discretion to enter into a consent decree or other similar agreement with a Covered Person as necessary to promote the safety, welfare, and integrity of Covered Horses, Covered Persons, and Covered Horseraces.

(d) Notice of Suspected or Actual Violation.

(1) The Authority, the Racetrack Safety Committee, or one or more stewards may issue a Notice of Suspected or Actual Violation to a Covered Person in any case in which the Authority has reason to believe that the Covered Person has violated or has failed to comply with any provision of regulations of the Authority. The notice shall:

(i) Identify the provision or provisions which the Covered Person is believed to have violated;

(ii) Specify with reasonable particularity the factual basis of the Authority's belief that the provision has been violated; and

(iii) Provide the Covered Person at least 7 days to respond, or a longer period as deemed appropriate and specified in the Notice based upon:

(A) The seriousness of the violation;

(B) The imminence of risk to Covered Persons, Covered Horses, Covered Horseraces, or the public; or

(C) Any other relevant factor.

(2) Upon receipt of the Notice of Suspected or Actual Violation, the Covered Person shall respond in writing to the issuing body within the time period specified in the notice. The Covered Person shall include in the response:

(i) A statement by the Covered Person admitting the violation or explaining the reasons why the Covered Person believes that a violation has not occurred;

(ii) All relevant details concerning the circumstances of the suspected or actual violation, including the results of any investigation undertaken by the Covered Person of the circumstances, and identification of any persons responsible for the circumstances; and

(iii) A detailed explanation of any remedial plan the Covered Person proposes to undertake to cure the suspected or actual violation and the date of the expected completion of the remedial plan.

(3) Upon receipt of the written response of the Covered Person, the issuing body may accept any proposed remedial plan, subject to any reasonable modifications the issuing body deems necessary, or it may initiate disciplinary proceedings in conformity with the provisions of Rule 8300. If the issuing body determines that no violation has occurred, the issuing body shall so inform the Covered Person and no further action shall be taken.

8300. Disciplinary Hearings and Accreditation Procedures

8310. Application

An alleged violation or failure to comply with the provisions of the Rule 2200 Series and any alleged violation of the rules set forth in Rule 8100 shall be adjudicated in accordance with this Rule 8300 Series, except that:

(a) An alleged violation of the anti-doping and medication control rule provisions in the Rule 3000 Series shall be adjudicated in accordance with the procedures set forth therein; and

(b) This regulation shall not apply to the adjudication of violations arising under state laws, racing rules, and regulations not preempted under 15 U.S.C. 3054(b).

8320. Adjudication of Violations in the Rule 2200 Series

(a) The stewards shall adjudicate all alleged violations of Rules 2271(b) or 2272 relating to the use of Shock Wave Therapy, Rule 2280 relating to the use of the riding crop, and Rule 2273 relating to the use of other electrical or mechanical devices. The stewards shall apply the hearing procedures of the state jurisdiction in which the violation is alleged to have occurred. Provided, however, that in any state that has not entered into an agreement with the Authority under which the state stewards serve in an adjudicatory capacity under the Rule 8000 Series and enforce the Rule 2200 Series, a hearing may be conducted by one or more stewards, notwithstanding any state rule to the contrary. All testimony at a stewards' hearing shall be given under oath, and a record of the hearing shall be kept by use of an audio recorder, video recording, or court reporter's transcript. Any ruling by the stewards finding a violation may be appealed to the Board of the Authority under the procedures described in Rule 8350. An appeal shall be filed in writing within 10 days of the issuance of the ruling by the stewards.

(b) With regard to any matter involving an alleged violation of a rule in the Rule 2200 Series other than those set forth in paragraph (a) above, the Racetrack Safety Committee may, at its discretion and taking into account the seriousness of the alleged violation and the facts of the case:

(1) Refer the matter to one or more members of the National Stewards Panel for adjudication in conformity with the procedures established in the Rule 7000 Series;

(2) Refer the matter to an independent Arbitral Body for adjudication in conformity with the procedures established in the Rule 7000 Series;

(3) Refer the matter to the stewards for adjudication in accordance with the hearing procedures of the applicable state jurisdiction. Provided, however, that in any state that has not entered into an agreement with the Authority under which the state stewards serve in an adjudicatory capacity under the Rule 8000 Series and enforce the Rule 2200 Series, a hearing may be conducted by one or more stewards, notwithstanding any state rule to the contrary; or

(4) Conduct a hearing upon the matter itself, under the procedures set forth in Rule 8340.

8330. Adjudication of Rule 8100 Violations

With regard to any matter involving an alleged violation of a rule established in Rule 8100, the Board of the Authority may, at its discretion and taking into account the seriousness of the violation and the facts of the case:

(a) Refer the matter to one or more members of the National Stewards Panel for adjudication in conformity with the procedures established in the Rule 7000 Series;

(b) Refer the matter to an independent Arbitral Body for adjudication in conformity with the procedures established in the Rule 7000 Series;

(c) Refer the matter to the stewards for adjudication in accordance with the hearing procedures of the applicable state jurisdiction. Provided, however, that in any state that has not entered into an agreement with the Authority under which the state stewards shall serve in an adjudicatory capacity under the Rule 8000 Series and enforce the Rule 2200 Series, a hearing may be conducted by one or more stewards, notwithstanding any state rule to the contrary; or

(d) Conduct a hearing upon the matter itself, under the procedures set forth in Rule 8340.

8340. Initial Hearings Conducted Before the Racetrack Safety Committee or the Board of the Authority

(a) An initial hearing before the Board shall be conducted by a panel of three Board members. The Board chair shall appoint the panel members and shall also designate one of them as the chair of the panel. At the discretion of the panel of the Board, an initial hearing may be conducted in person or by means of an audio-visual teleconferencing system or a telephone audio system.

(b) An initial hearing before the Racetrack Safety Committee shall be heard by a quorum of the Racetrack Safety Committee. The Racetrack Safety Committee Chair shall act as the chair of the hearing panel unless the Chair is unavailable, in which case the Racetrack Safety Committee Chair shall designate a member of the quorum to act as the chair of the panel. At the discretion of the Racetrack Safety Committee, an initial hearing may be conducted in person or by means of an audio-visual teleconferencing system or a telephone audio system.

(c) Persons entitled to notice of a hearing before the Board or the Racetrack Safety Committee shall be informed not less than 20 days prior to the hearing of:

(1) The time, place, and nature of the hearing;

(2) The legal authority and jurisdiction under which the hearing is to be held;

(3) A description of the rule or rules allegedly violated, specifying by number the rule allegedly violated; and

(4) A statement of the factual basis of the alleged violation in sufficient detail to provide adequate opportunity to prepare for the hearing.

(d) At any time prior to, during, or after the hearing, the Board or the Racetrack Safety Committee in its discretion may require the submission of written briefs or other information as will assist in the hearing of the matter.

(e) All testimony in proceedings before the Board or the Racetrack Safety Committee shall be given under oath,

and a record of the proceedings shall be kept in stenographic or recorded form.

(f) The burden of proof shall be on the party alleging the violation to show, by a preponderance of the evidence, that the Covered Person has violated or failed to comply with a provision of or is responsible for a violation of a provision of the Authority's regulations.

(g) The Board or the Racetrack Safety Committee shall allow a full presentation of evidence and shall not be bound by the technical rules of evidence. However, the Board or the Racetrack Safety Committee may disallow evidence that is irrelevant or unduly repetitive of other evidence. The Board or the Racetrack Safety Committee shall have the authority to determine, in its sole discretion, the weight and credibility of any evidence or testimony. The Board or the Racetrack Safety Committee may admit hearsay evidence if it determines the evidence is of a type that is commonly relied on by reasonably prudent people. Any applicable rule of privilege shall apply in hearings before the Board or the Committee.

(h) A party shall be entitled to present its case or defense by oral or documentary evidence, to be represented by counsel at the party's expense, to submit rebuttal evidence, and to conduct such limited cross-examination as may be required for a full and true disclosure of the facts.

(i) Presiding Officer for the Conduct of the Hearing. The Board or the Racetrack Safety Committee may appoint a presiding officer to assist in regulating the orderly conduct of and presentation of evidence at the hearing. The Board or the Racetrack Safety Committee may assign to the presiding officer any or all of the following powers, in any manner that the Board or Racetrack Safety Committee determines is most appropriate based upon the nature and complexity of the subject matter of the hearing. The presiding officer may be granted the power to:

(1) Rule upon requests, including all requests for adjournments;

(2) Set the time and place of hearing, recesses, and adjournments;

(3) Administer oaths and affirmations;

(4) Summon and examine witnesses, including the authority to direct a party to appear and to testify;

(5) Order that opening and closing statements be made;

(6) Admit or exclude evidence;

(7) Allow oral argument, so long as it is recorded;

(8) Issue orders limiting the scope and length of cross-examination, the length of briefs, and other similar matters;

(9) Order the parties to appear for a prehearing conference to consider matters that may simplify the issues or expedite the proceeding; and

(10) Perform all acts and take all measures necessary for the maintenance of order and the efficient conduct of the hearing.

(j) Presiding Officer for the Submission of a Hearing Report. The Board or the Racetrack Safety Committee may direct a presiding officer to issue in writing a hearing report at the conclusion of the hearing and to submit it to the Board or the Racetrack Safety Committee and all parties. A copy of the record of the hearing shall accompany the hearing report. The hearing report shall set forth findings of fact, conclusions of law, and a recommended disposition. If the presiding officer finds that imposition of a penalty under Rule 8200 upon a party to the hearing is warranted, the recommended penalty shall be set forth in specific detail, including the length of any suspension and the amount of any fine. If so directed by the Board or the Racetrack Safety Committee, the presiding officer shall establish a schedule for the filing by the parties of:

(1) Briefs to be considered by the presiding officer prior to the presiding officer's preparation of the hearing report; and

(2) Exceptions to the presiding officer's hearing report after the hearing report has been delivered to the parties. The exceptions may include for consideration and adoption by the Board or the Racetrack Safety Committee the particular findings of fact, conclusions of law, and recommendations for disposition with which the party disagrees and the reasons for such disagreement, any general comments by the party on the suitability of the hearing report, and the party's alternative proposed findings of fact, conclusions of law, and recommendations for disposition. A party shall send a copy of its exceptions to all other parties or their attorneys and presiding officer.

(k) Review by the Board or the Racetrack Safety Committee. Upon receipt of the record of the hearing, and of any hearing report and exceptions thereto submitted pursuant to paragraph (j), the Board or the Racetrack Safety Committee shall review the record and submissions. The period for review shall not exceed 20 days unless extended by the Board or the Racetrack Safety Committee upon notice to all parties.

(*l*) Written Decision. The Board or the Racetrack Safety Committee shall issue to all parties within 30 days of the close of the review period a written decision setting forth findings of fact, conclusions of law, and the disposition of the matter including any penalty imposed. If a hearing report has been received, the Board and the Racetrack Safety Committee shall have discretion to adopt, modify, or reject any or all of the hearing report including, but not limited to, the appropriate disposition of the proceeding and any penalty recommended.

8350. Appeal to the Board

(a) Any decision rendered by the Racetrack Safety Committee, the stewards, the National Stewards Panel, or an Arbitral Body may be appealed on the record to the Board. The decision may be appealed by a party to the decision, or the decision may be reviewed upon the Board's own initiative and at its discretion.

(b) Any decision rendered by an initial Board hearing panel may be appealed on the record to the Board, to be reviewed by a quorum of the Board which shall not include the Board members who were on the panel in the initial hearing. The decision may be appealed by a party to the decision, or the decision may be reviewed upon the Board's own initiative and at its discretion.

(c) An appeal shall not automatically stay the decision. A party may request the Board to stay the decision. A stay may be issued by the Board, or any official or body of the Authority to whom the Board delegates the authority to review requests for stay, for good cause shown.

(d) A party to the decision may appeal to the Board by filing with the Board a written request for an appeal within 10 days of receiving a written order. The appeal request shall contain the following information:

(1) The name, address, and telephone number, if any, of the appellant;

(2) A description of the objections to the decision;

(3) A statement of the relief sought; and

(4) Whether the appellant desires to have a hearing of the appeal.

(e) The Board may in its discretion review a decision based solely upon written submissions scheduled for filing with such timing and response requirements as the Board may require. Alternatively, or in addition to written submissions, the Board may set a date, time, and place for a hearing. Notice shall be given to the appellant in writing and shall set out the date, time, and place of the hearing, and shall be served personally or sent by electronic or U.S. mail to the last known address of the

appellant. If the appellant objects to the date of the hearing, the appellant may obtain a continuance, but the continuance shall not automatically stay imposition of a sanction or prolong a stay issued by the Board. At the discretion of the Board, the hearing may be conducted in person or by means of an audio-visual videoconferencing system or a telephone audio system.

(f) Upon review of the decision that is the subject of the appeal, the Board shall uphold the decision unless it is clearly erroneous or not supported by the evidence or applicable law.

(g) Upon completing its review, the Board may:

(1) Accept the decision;

(2) Reject or modify the decision, in whole or in part;

(3) Remand the matter, in whole or in part, to the stewards, Racetrack Safety Committee, the National Stewards Panel, or an Arbitral Body, as the case may be, for further proceedings as appropriate; or

(4) Conduct further proceedings on the matter as appropriate, including but not limited to requiring the submission of written briefs or, in extraordinary circumstances and at the Board's discretion, the taking of additional testimony before the Board under oath.

(h) The Board may appoint a presiding officer to assist in regulating the orderly conduct of and presentation of evidence at a hearing in accordance with Rule 8340(i). The Board may also direct a presiding officer to issue in writing a hearing report at the conclusion of the hearing in accordance with Rule 8340(j).

(i) The Board shall issue its written decision based on the record and any further proceedings, testimony, or hearing report and exceptions thereto submitted in accordance with Rule 8340(k). If a hearing report and exceptions have been submitted, the Board's written decision shall in accordance with Rule 8340(*l*) include findings of fact, conclusions of law, and the disposition of the matter including any penalty imposed. The Board shall not be bound by the timing provisions in Rules 8340(k) and (*l*) relating to the period for review and the issuance by the Board of its written decision. A copy of the Board's decision shall be served upon all parties by first class mail, electronic mail, or personal service.

(j) The decision of the Board shall be the final decision of the Authority.

8360. Accreditation Procedures

(a) Any decision issued by the Authority denying, suspending, or revoking racetrack accreditation may:

(1) Be appealed within 10 days by the Racetrack to the Authority for a de novo hearing reviewing the Authority's decision; or

(2) Reviewed by the Authority on its own initiative.

(b) The Authority's order suspending or revoking accreditation shall be stayed automatically pending review of the decision by the Authority.

(c) At its discretion, the Authority may request and consider any additional information from any source that may assist in the review.

(d) The Racetrack may request to make a presentation before the Authority concerning racetrack safety and any remedial efforts proposed to be undertaken by the Racetrack. At its discretion, the Authority may permit the Racetrack to make such presentation.

(e) In conducting its review, that Authority may consider all factors that it deems appropriate, including but not limited to:

(1) The extent and magnitude of any deficiencies in racetrack operations conducted at the Racetrack;

(2) The threat posed by the deficiencies to the safety and integrity of horseracing conducted at the Racetrack;

(3) The adequacy of the efforts the Racetrack proposes to undertake or has undertaken to remedy all deficiencies at the Racetrack;

(4) The likelihood and timeframe within which compliance will be achieved by the Racetrack, given the resources available to the Racetrack and the past record of the Racetrack in achieving and maintaining compliance with the rules of the Authority; and

(5) Any other factors the Authority deems relevant to its review.

(f) Upon completing its review, the Authority may take one or more of the following actions:

(1) Order that the Racetrack's accreditation be denied, suspended, or revoked, upon a vote in favor of denial or revocation by two-thirds of a quorum of the members of the Board;

(2) Reinstate accreditation subject to any requirements the Authority deems necessary to ensure that horseracing will be conducted in a manner consistent with racetrack safety and integrity. The Authority may also impose a fine upon reinstatement in an amount not to exceed $50,000.00. The Authority may require the Racetrack to report at prescribed intervals on the status of racetrack safety operations and remedial efforts to improve safety pursuant to the Authority's racetrack safety rules; or

(3) Prohibit a Racetrack from conducting any Covered Horserace.

8370. Final Civil Sanction

Any decision rendered by the Board of the Authority under Rule 8350, or the Authority under Rule 8360, shall constitute a final civil sanction subject to appeal and review in accordance with the provisions of 15 U.S.C. 3058.

8380. Guidelines for Confidentiality and Public Reporting

As used in this Rule, ''public disclosure'' means the dissemination or distribution of information by the Authority to the general public.

(a) This Rule shall apply to an alleged violation of any provision of the Act, the Rule 2000 Series, the Rule 8000 Series, or the Rule 9000 Series. It shall not apply to:

(1) An alleged violation of the anti-doping and medication control rule provisions in the Rule 3000 Series; or

(2) An alleged violation arising under state laws, racing rules, and regulations not preempted under 15 U.S.C. 3054(b).

(b) After notice of a violation of any provision in the Rule 2200 Series, the Rule 8000 Series, or the Rule 9000 Series has been provided to a Covered Person by the Authority or any official or body authorized to adjudicate violations under the Rule 8000 Series, the Authority shall publicly disclose the following information relating to the alleged violation:

(1) The identity of any Covered Person who is the subject of the alleged violation;

(2) The identity of any applicable horse; and

(3) The rule violated and, where appropriate, the basis of the asserted violation.

(c) Information as described in paragraph (b) concerning a violation of the Rule 2100 Series shall be disclosed in accordance with this Rule by the Authority either upon issuance of a Notice of Suspected or Actual Violation, or at any time thereafter, as deemed appropriate by the Authority.

(d) If at any time information pertaining to an alleged violation is publicly disclosed by the Covered Person charged with the violation or any employee or agent of the Covered Person, the Authority may comment on the information publicly disclosed by the Covered Person.

(e) The Authority shall not be required to make public disclosure if public disclosure will compromise an ongoing investigation or proceeding. When the Authority determines that an ongoing investigation or proceeding will no longer be compromised by public disclosure, the Authority shall at such time make any public disclosure required under this Rule.

(f) Notwithstanding any provision to the contrary in the rules of the Authority, the Authority may make public disclosure of any relevant information at any time, including prior to delivery of notice of a violation, if the Authority determines that such disclosure:

(1) Concerns a violation or circumstance that poses a serious and imminent risk of harm to Covered Persons, Covered Horses, or the public; or

(2) Is otherwise in the best interest of horseracing conducted at Covered Horseraces.

(g) The Authority shall publicly disclose the resolution of an alleged violation no later than 20 calendar days after the earlier of:

(1) The imposition of a final civil sanction;

(2) A resolution between the Authority and the Covered Person; or

(3) The dismissal of the allegation or a finding of no violation by the Authority.

(h) Public disclosure under paragraph (g)(1) & (2) shall include the following:

(1) The name of the Covered Person who committed the violation and any Covered Horse affected by the violation;

(2) The Rule violated;

(3) The sanction imposed;

(4) The order or other ruling issued in the matter; and

(5) The results of any appellate decisions concerning the violation.

(i) Public Disclosure shall not be required under this Rule if the Covered Person alleged to have committed a violation is a minor. Public disclosure concerning a case involving a minor shall be at the discretion of the Authority and in proportion to the facts and circumstances of the case.

(j) Publication shall be accomplished at a minimum by placing the required information on the Authority's website or publishing it through other means.

(k) Pursuant to 15 U.S.C. 3054, this Rule shall preempt any provision of State law or regulation, including those pertaining to data practice and privacy laws.

8400. Investigatory Powers

(a) The Commission, the Authority, or their designees:

(1) Shall have free access to:

(i) With regard to Covered Persons, books, records, offices, racetrack facilities, and other places of business of Covered Persons that relate to the care, treatment, training, and racing of Covered Horses; and

(ii) With regard to any person who owns a Covered Horse or performs services on a Covered Horse, books, records, offices, facilities, and other places of business that relate to the care, treatment, training, and racing of Covered Horses.

(2) May seize any medication, drug, substance, or paraphernalia in violation or suspected violation of any provision of 15 U.S.C. Chapter 57A or the regulations of the Authority, and any object or device reasonably believed to have been used in furtherance of the violation or suspected violation.

(b) Upon final resolution of a violation, the Commission, the Authority, or their designees shall return seized property, including but not limited to phones, computers, and other repositories of electronic data, the possession of which is not specifically prohibited by the Act or the rules of the Authority.

(c) A Covered Person shall:

(1) Cooperate with the Commission, the Authority, or their designees during any investigation; and

(2) Respond truthfully to the best of the Covered Person's knowledge if questioned by the Commission, the Authority, or their designees about a racing matter.

(d) A Covered Person or any officer, employee, or agent of a Covered Person shall not hinder a person who is conducting an investigation under or attempting to enforce or administer any provision of 15 U.S.C. Chapter 57A or the regulations of the Authority.

(e) The Commission or the Authority may issue subpoenas for the attendance of witnesses in proceedings within their jurisdiction, and for the production of documents, records, papers, books, supplies, devices, equipment, and all other instrumentalities related to matters within the jurisdiction of the Commission or the Authority.

(f) Failure to comply with a subpoena or with the other provisions of this Rule may be penalized by the imposition of one or more penalties set forth in Rule 8200.

(g) The Commission or the Authority may administer oaths to witnesses and require witnesses to testify under oath in matters within the jurisdiction of the Commission or the Authority.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2022–15972 Filed 7–25–22; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; ACF Performance Progress Report, ACF–OGM–SF–PPR–B (OMB #0970–0406)

AGENCY: Office of Grants Management, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Grants Management (OGM), in the Administration for Children and Families (ACF) is requesting a 3-year extension of the form ACF–OGM–SF–PPR–B (OMB #0970–406, expiration 11/30/2022). There are minor changes requested to the form.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF's OGM is proposing the continued collection of program performance data for ACF's discretionary grantees using the existing ACF–OGM–SF–PPR–B (OMB #0970–0406, expiration 11/30/2022) form with minor changes to improve the function of the form. Revisions include collection of the Unique Entity Identifier instead of the Data Universal Numbering System, a rewording of the submission instructions to be more inclusive of all possible report submission methods utilized across ACF, and the addition of a program indicator to collect information on activities recipients conducted during the reporting period to address or advance equity. The form, developed by OGM, was created from the basic template of the OMB-approved reporting format of the Program

Performance Report. OGM uses this data to ensure grantees are proceeding in a satisfactory manner in meeting the approved goals and objectives of the project and if funding should be continued for another budget period.

OMB grants policy requires grantees to report on performance. Specific citations are contained in 45 CFR part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

Respondents: All ACF discretionary grantees. State governments, Native American Tribal governments, Native American Tribal Organizations, local governments, universities, and nonprofits with or without 501(c)(3) status with the IRS.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ACF–OGM–SF–PPR–B	6,000	2	1	12,000

Estimated Total Annual Burden Hours: 12,000.

Authority: 45 CFR part 75.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–15940 Filed 7–25–22; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0863]

Agency Information Collection Activities; Proposed Collection; Comment Request; Monthly Monitoring Study

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed information collection entitled ''Monthly Monitoring Study.''

DATES: Either electronic or written comments on the collection of information must be submitted by September 26, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 26, 2022. 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–2022–N–0863 for the ''Monthly Monitoring Study'' 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, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Monthly Monitoring Study

OMB Control Number 0910–NEW

This information collection supports the development and implementation of FDA public education campaigns related to tobacco use. To reduce the public health burden of tobacco use in the United States and educate the public—especially young people—about the dangers of tobacco use, FDA's Center for Tobacco Products is developing and implementing multiple public education campaigns.

FDA launched ''The Real Cost'' in February 2014, seeking to reduce tobacco use among at-risk youth ages 12–17 in the United States who are open to smoking cigarettes and/or using electronic nicotine delivery systems (ENDS) products, or have already experimented with cigarettes and/or ENDS products. Given the rapidly evolving tobacco landscape in the United States, frequent and nimble data collection strategies are needed to keep pace and provide relevant information to FDA to inform its tobacco prevention media campaign development about changes in tobacco use and emerging products among youth and young adults.

In an effort to inform specified recommendations around ''The Real Cost'' and FDA's other public education programs to reduce tobacco-related death and disease, more research is needed to understand the trends in use and perceptions of novel and emerging tobacco products, as well as awareness and preferences related to emerging tobacco products and specific brands and device types so that the FDA can develop new media campaign messages that resonate with youth and young adults. The purpose of the Monthly Monitoring Study is to collect primary data from youth and young adults, ages 15 to 24 years old, in the United States to monitor perceptions and use of emerging and novel tobacco products and emerging trends in brand and device awareness and use.

The study will be conducted using web-based surveys that are self-administered on personal computers or web enabled mobile devices. The study will use an online survey to collect data from up to 27,000 youth and young adults ages 15 to 24 years to monitor perceptions about and trends in use of ENDS and other emerging tobacco products. Participants will be recruited through social media advertisements. To achieve the required pace of data collection, the study will not contact parents of youth under 18 years old for parental permission and will obtain a waiver of parental permission from the institutional review board. The study will include questions about marijuana use to allow the study team to differentiate between use of current and emerging tobacco products and marijuana, which can be used in tobacco products such as ENDS and little cigar/cigarillos. The survey will take approximately 20 minutes to complete per participant. This survey will ask participants to provide feedback on tobacco use and quitting behavior, as well as brand and device preferences, tobacco information sources, peer influence and perceptions, and marijuana use.

The aim of the Monthly Monitoring Study is to answer the following questions:

- What are the trends in brand and device use for ENDS products and other emerging tobacco products among youth and young adults ages 15 to 24 years in the United States? What are their perceptions of these products?
- How is respondent tobacco use affected by environmental factors, including peer influence and other external factors such as COVID–19?
- What are the primary sources of new product information and where are these products purchased/acquired?
- What are the primary sources of health information for ENDS and other emerging tobacco products?

In support of the provisions of the Family Smoking Prevention and Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect data for the Monthly Monitoring Study.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Youth Screener	27,000	1	27,000	0.04167 (2.5 minutes)	1,125
Youth Assent	13,500	1	13,500	0.04167 (2.5 minutes)	563
Youth Online Survey	13,500	1	13,500	0.3333 (20 minutes)	4,500
Young Adult Screener	27,000	1	27,000	0.04167 (2.5 minutes)	1,125
Young Adult Consent	13,500	1	13,500	0.04167 (2.5 minutes)	563

TABLE 1—ESTIMATED REPORTING BURDEN [1]—Continued

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Young Adult Online Survey	13,500	1	13,500	0.3333 (20 minutes)	4,500
Total					12,376

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We expect the screening process (2.5 minutes per response) to yield a 2 to 1 ratio of eligible participants. We will need to screen approximately 54,000 potential participants (27,000 youth and 27,000 young adults) over the study period. Participants determined to be eligible through the screener will complete a youth assent or young adult consent (2.5 minutes per response) and the online survey (20 minutes per response).

Over the course of the study period, we intend to survey approximately 1,500 youth ages 15–17, and young adults ages 18–24, every 1 to 2 months. The survey will be repeated with a new cross-sectional sample approximately every month or every other month over a period of 18 months. We will obtain a final sample size of 27,000 youth and young adults (13,500 youth and 13,500 young adults) over the course of the study period. Respondents will be allowed to complete an additional, cross-sectional survey after 6 months.

Dated: July 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15955 Filed 7–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1729]

Revocation of Emergency Use of a Drug During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Gilead Sciences, Inc. (Gilead) for VEKLURY (remdesivir). FDA revoked the Authorization on April 25, 2022, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) given the approval of a supplemental new drug application (NDA) for VEKLURY, which expanded the approved indication to cover the authorized population. The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization is revoked as of April 25, 2022.

ADDRESSES: Submit written requests for single copies of the Authorization and/or revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On May 1, 2020, FDA issued an Authorization (EUA 046) to Gilead for remdesivir, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on September 11, 2020 (85 FR 56231), as required by section 564(h)(1) of the FD&C Act. Subsequent amendments to the Authorization on August 28, 2020, October 1, 2020, October 16, 2020, October 22, 2020, and January 21, 2022, were made available on FDA's website.

II. EUA Criteria for Issuance No Longer Met

Under section 564(g)(2) of the FD&C Act, the Secretary of HHS may revoke an EUA if, among other things, the criteria for issuance are no longer met. On April 25, 2022, FDA revoked the EUA for VEKLURY because the criteria for issuance were no longer met. Under section 564(c)(3) of the FD&C Act, an EUA may be issued only if FDA concludes there is no adequate, approved,[1] and available alternative to the product for diagnosing, preventing, or treating the disease or condition. On April 25, 2022, FDA approved a supplemental NDA to NDA 214787 for VEKLURY, which expanded the approved indication to the following:

> Veklury is a severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) nucleotide analog RNA polymerase inhibitor indicated for the treatment of coronavirus disease 2019 (COVID–19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV–2 viral testing, who are:
> - Hospitalized, or
> - Not Hospitalized and have mild-to-moderate COVID–19 and are at high risk for progression to severe COVID–19, including hospitalization or death.

FDA has concluded that VEKLURY approved under NDA 214787 is an adequate, approved, and available alternative to the VEKLURY available for emergency use for the treatment of COVID–19 for purposes of section 564(c)(3) of the FD&C Act. Accordingly, FDA revoked EUA 046 for emergency use of VEKLURY, pursuant to section 564(g)(2) of the FD&C Act.

III. Electronic Access

[1] In the context of section 564, the term ''approved'' refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), or 360(e)) or section 351 of the Public Health Service Act (42 U.S.C. 262). See section 564(a)(2) of the FD&C Act.

An electronic version of this document and the full text of the Authorization and revocation are available on the internet from *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization* and *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Gilead's VEKLURY (remdesivir). The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

April 25, 2022

Gilead Sciences, Inc.
Attention: Madelyn Low, MBS
Manager, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

RE: Emergency Use Authorization 046

Dear Ms. Low:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA 046) for emergency use of Gilead Sciences, Inc.'s ("Gilead") Veklury (remdesivir), issued initially on May 1, 2020, and amended on August 28, 2020, October 1, 2020, October 16, 2020, October 22, 2020, and January 21, 2022.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved[1], and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

On April 25, 2022, the Agency approved a supplemental New Drug Application (NDA) to NDA 214787, which expanded the approved indication to the following:

> *Veklury is a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleotide analog RNA polymerase inhibitor indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV-2 viral testing, who are:*
>
> - *Hospitalized, or*
> - *Not Hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.*

Page 2 – Ms. Low, Gilead Sciences, Inc.

Based on this approval, FDA has concluded that NDA 214787 for Veklury is an adequate, approved[1], and available alternative to Veklury available for emergency use, for the treatment of COVID-19 for purposes of section 564(c)(3) of the Act.

Accordingly, FDA revokes EUA 046 for emergency use of Veklury, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the Veklury that was authorized by FDA for emergency use under EUA 046 is no longer authorized by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

[1] In the context of section 564, the term "approved" refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15956 Filed 7–25–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0862]

Agency Information Collection Activities; Proposed Collection; Comment Request; The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice

solicits comments on a proposed information collection titled ''The Real Cost Campaign Outcomes Evaluation Study: Cohort 3.''

DATES: Submit either electronic or written comments on the collection of information by September 26, 2022.

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 26, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 26, 2022. 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–2022–N–0862 for ''The Real Cost Campaign Outcomes Evaluation Study: Cohort 3.'' 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, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

OMB Control Number 0910—NEW

This information collection supports the development and implementation of FDA public education campaigns related to tobacco use. To reduce the public health burden of tobacco use in the United States and educate the public—especially young people—about the dangers of tobacco use, the FDA Center for Tobacco Products (CTP) is developing and implementing multiple public education campaigns.

FDA launched ''The Real Cost'' in February 2014, seeking to reduce tobacco use among at-risk youth ages 12–17 in the United States who are open to smoking cigarettes and/or using electronic nicotine delivery systems (ENDS) products, or have already experimented with cigarettes and/or ENDS products. Complementary

evaluation studies, including the ''Evaluation of FDA's Public Education Campaign on Teen Tobacco (ExPECTT),'' were designed and implemented to measure awareness of and exposure to ''The Real Cost'' paid media campaign among youth ages 12–17 in targeted areas of the United States.

The first cohort (ExPECTT: Cohort 1) assessed the campaign's impact on outcome variables of interest from November 2013 to November 2016. The second cohort (ExPECTT: Cohort 2) has been assessing the campaign's impact on outcome variables of interest from June 2018 and will run through August 2022. To continue assessing the impact of ''The Real Cost'' campaign, FDA will implement The Real Cost Campaign Outcomes Evaluation Study: Cohort 3. The study will consist of four waves of data collection, including the baseline survey and three followup (FU) surveys. Online surveys with youth ages 11–20 will be conducted at baseline.

Online surveys of youth will be conducted in the United States to measure the effectiveness of FDA's ''The Real Cost'' campaign. The purpose of FDA's The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 is to provide credible evidence that changes in key outcomes can be attributed to exposure to the campaign. The strength of the attribution is determined by the ability of the evaluation approach to rule out alternative explanations for observed changes in key outcomes. Attributing effects to a campaign require using multiple, complementary methods that build a case that exposure to the campaign leads to changes in key outcomes. For a national campaign evaluation, FDA can improve attribution by carefully assessing potential confounders. To improve attribution, we intend to measure variation in both potential campaign exposure (*e.g.,* market-level delivery) and self-reported campaign exposure to media advertising.

The goal of The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 is to determine whether future waves of ''The Real Cost'' public education campaign will influence any of the following key outcomes:

- Awareness of campaign messages
- Specific beliefs targeted by messages (message-targeted beliefs)
- Psychosocial predictors or precursors of tobacco use behavior
  - Health and addiction risk perceptions
  - Perceived loss of control or threat to freedom expected from tobacco use
  - Anticipated guilt, shame, and regret from tobacco use
  - Perceptions of prevalence, approval, and popularity of tobacco use
  - Pro-health changes in normative beliefs about tobacco product use
  - Tobacco use susceptibility
  - Intention or willingness to use tobacco
  - Intention to quit and/or reduce daily consumption

In support of the provisions of the Tobacco Control Act (Pub. L. 11–31) that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information to evaluate CTP's public education campaign ''The Real Cost'' through the Evaluation Study: Cohort 3.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Parent Recruitment Study Materials—Main: Baseline & Followup 2 Replenishment	545,000	1	545,000	0.17 (10 mins)	92,650
Parent Screener—Main: Baseline & Followup 2 Replenishment	272,500	1	272,500	0.08 (5 mins)	21,800
Household Roster—Main: Baseline & Followup 2 Replenishment	5,500	1	5,500	0.08 (5 mins)	440
CATI Screener—Main: Baseline & Followup 2 Replenishment	2,000	1	2,000	0.08 (5 mins)	160
Parent Permission—Main: Baseline & Followup 1,2,3	21,600	1	21,600	0.08 (5 mins)	1,728
Youth Assent—Main: Baseline & Followup 1,2,3	21,600	1	21,600	0.08 (5 mins)	1,728
Youth Survey—Main: Baseline & Followup 1,2,3	21,600	1	21,600	0.50 (30 mins)	10,800
Youth Screener—Supplemental	5,000	1	5,000	0.08 (5 mins)	400
Youth Assent—Supplemental: Baseline & Followup 1,2,3	4,428	1	4,428	0.08 (5 mins)	355
Youth Survey—Supplemental: Baseline & Followup 1,2,3	4,428	1	4,428	0.50 (30 mins)	2,214
Total					132,275

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Main Data Collection

The main data collection will include a baseline survey and three FU surveys. The recruitment sample for the main data collection is youth ages 11–17. We intend to replenish the longitudinal sample at FU2 to obtain 6,000 youth respondents to maintain at least 4,800 respondents at each wave. We expect the screening process to yield a 100:1 ratio of eligible responding households. We estimate that we will mail 400,000 recruitment/study material packages (10 minutes per response) in order to receive at least 200,000 completed screeners (5 minutes per response) by adults within households. Households completing the screener by mail will be contacted to complete a computer-assisted telephone interview (CATI) where an interviewer will determine eligibility and obtain parental permission (5 minutes per response). For households identified as eligible for the study during the screening process (*i.e.,* the presence of one or more youth ages 11 to 17), we will ask the parent/guardian to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). We estimate from the 200,000 completed screeners, we will recruit 6,000 eligible youth from the 4,000 eligible households.

Baseline

At baseline, we plan to collect data from approximately 6,000 youth respondents from the 4,000 eligible households identified through screening. More than one eligible youth

per household may be recruited for the study. These 6,000 youth respondents are estimated to provide baseline assent (5 minutes per response) and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study. We estimate that we will lose approximately 20 percent of the original baseline sample at each FU wave.

Followup 1

We estimate that we will retain 80 percent of the sample from baseline and collect data from 4,800 respondents (5 minutes per response) at FU1. These 4,800 youth respondents are estimated to provide assent (5 minutes per response) for FU1 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study. We do not intend to replenish the sample at FU1.

Followup 2

We estimate that we will retain 80 percent of the sample from FU1 resulting in 3,840 respondents at FU2. To replenish the longitudinal sample at FU2, we will send additional ''baseline'' screeners to new households. We intend to send recruitment/study material packages to an additional 145,000 households (10 minutes per response) to receive an estimated 72,500 completed screeners (5 minutes per response). For households identified as eligible for the study during the screening process (*i.e.,* the presence of 1 or more youth ages 11 to 17), we will ask the parent/guardian to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). Households completing the screener by mail will be contacted to complete a CATI where an interviewer will determine eligibility and obtain parental permission (5 minutes per response). From these completed screeners, we estimate that we will obtain data from an additional 2,160 youth within approximately 1,500 households. Replenishing the sample will allow us to obtain 6,000 youth respondents at FU2 (3,840 from the original sample, and 2,160 from the replenishment sample) and maintain a minimum study sample of 4,800 respondent at all study waves. These 6,000 youth respondents are estimated to provide assent (5 minutes per response) for FU2 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study.

Followup 3

We estimate that we will retain 80 percent of the sample from FU2 and collect data from 4,800 respondents at FU3. We do not intend to replenish the sample at FU3. These 4,800 youth respondents are estimated to provide assent (5 minutes per response) for FU2 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study.

Supplemental Data Collection

In addition to the main data collection, we intend to collect data from subpopulations shown to be at higher risk of initiating use of cigarettes and ENDS products, such as youth who identify as LGBTQ+ and youth who have a mental health disorder. Data collection will consist of online self-administered surveys of participants recruited through social media advertisements. The recruitment sample for this data collection will be youth ages 14 to 20 who meet the subpopulation criteria. We intend to collect data at baseline from 1,500 respondents. We anticipate that we will need to screen 5,000 respondents (5 minutes per response) to obtain a baseline sample of 1,500 respondents who meet the subpopulation criteria. At baseline, we plan to collect data from approximately 1,500 respondents identified as eligible through screening. These 1,500 youth respondents are estimated to provide assent (5 minutes per response) and complete the survey (30 minutes per response). We estimate that we will lose approximately 20 percent of the original baseline sample at each FU wave; therefore, estimating 1,200 respondents at FU1, 960 respondents at FU2, and 768 respondents at FU3. For the FU samples, youth will provide assent (5 minutes per response) and complete the survey (30 minutes per response).

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15954 Filed 7–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Human Genome Research.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.

Date: August 1, 2022.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100 Bethesda, MD 20892, (301) 402–0838, *pozzattr@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Information is also available on the Institute's/Center's home page: *http://www.genome.gov/council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 20, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–15908 Filed 7–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov.* Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Lymphatic Filariasis Biomarkers for Detection and Surveillance

Description of Technology: Lymphatic filariasis (elephantiasis; LF) is a neglected tropical disease that affects over 120 million people throughout the tropics and subtropics of Asia, Africa, the Western Pacific, and parts of the Caribbean and South America. LF results from infection with the filarial parasites *Wuchereria bancrofti* or *Brugia malayi.* Current methods of confirming active infection by *W. bancrofti* or *B. malayi* include microscopy and immunoassays using serum/plasma extracted from the patient. However, the sensitivity of microscopy detection varies among patients, and immunoassays show cross-reactivity with antibodies directed towards other parasites, such as *Onchocerca volvulus* or *Loa loa* whose geographic distribution can overlap with the LF-causing filarial parasites.

This new technology addresses the limitations of cross-reactivity through the detection of a single antigen, Wb5B, selected due to a lack of homologs in other filarial parasites that infect humans. Preliminary data indicates that Wb5B is immunogenic, highly specific (>99%), and accurate (>90%) for the detection of *W. bancrofti* infection in sera from humans and other mammalian sources. The antigen can be isolated in soluble form for integration in a variety of diagnostic assay formats.

The subject technology, including the antigen sequence as well as plasmids enabling bacterial, insect, and mammalian cell expression, is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

There may be the potential to combine this technology with another NIAID-developed biomarker technology (Wb123, available for licensing; see HHS Ref. No. E–281–2010–0, ''Diagnostic Assays and Methods of Use for Detection of Filarial Infection'') for the development of a multiplex assay for detection of active *W. bancrofti* infection for diagnostic or surveillance purposes.

Potential Commercial Applications:

- Diagnostics for *W. bancrofti* infection
- Surveillance for *W. bancrofti* prevalence

Competitive Advantages:

- Increased specificity compared to available diagnostics
- Differentiation from other parasites with similar geographic footprints

Development Stage: Pre-Clinical.

Inventors: Thomas B. Nutman, Sasisekhar Bennuru, both of NIAID.

Intellectual Property: U.S. Provisional Patent Application Serial No. 63/347,794, filed June 1, 2022.

Related Inventions: Diagnostic Assays and Methods of Use for Detection of Filarial Infection (HHS Reference No. E–281–2010–0).

Licensing Contact: To license this technology, please contact Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov.,* and reference E–093–2022–0.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov.*

Dated: July 14, 2022.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2022–15910 Filed 7–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel; COI–R01–K99–R13.

Date: December 2, 2022.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Video Assisted Meeting.

Contact Person: Jan Li, M.D., Ph.D., Scientific Review Officer, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892–7968, 301–496–3114, *lij21@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–15909 Filed 7–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0343; OMB Control Number 1625–0126]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0126, Requirements for Vessels that Perform Certain Aquaculture Support Operations; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before September 26, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0343] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0343], and must be received by September 26, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Requirements for Vessels that Perform Certain Aquaculture Support Operations.

OMB Control Number: 1625–0126.

Summary: This information is required to ensure that a vessel engaged in certain aquaculture operations has applied for and received a waiver in accordance with 46 U.S.C. 12102(d)(1). A vessel owner or operator must notify Coast Guard and provide a copy of the waiver.

Need: The Coast Guard regulations are prescribed 46 CFR part 106. The Coast Guard uses the information in this collection to ensure compliance with the requirements.

Forms: None.

Respondents: Owners and operators of aquaculture operations.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 2 hours to 3 hours a year, due to an increase in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: July 20, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–15899 Filed 7–25–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0342; OMB Control Number 1625–0105]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0105, Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District and the Illinois Waterway, Ninth Coast Guard District; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before September 26, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0342] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and

request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0342], and must be received by September 26, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District and the Illinois Waterway, Ninth Coast Guard District.

OMB Control Number: 1625–0105.

Summary: The Coast Guard requires position and intended movement reporting, and fleeting operations reporting, from barges carrying certain dangerous cargoes (CDCs) in the inland rivers within the Eighth and Ninth Coast Guard Districts. The reporting requirements are found in 33 CFR 165.830 and 165.921.

Need: This information is used to ensure port safety and security and to ensure the uninterrupted flow of commerce.

Forms: N/A.

Respondents: Owners, agents, masters, towing vessel operators, or persons in charge of barges loaded with CDCs or having CDC residue operating on the inland rivers located within the Eighth and Ninth Coast Guard Districts.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 4 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: July 20, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–15898 Filed 7–25–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0341; OMB Control Number 1625–0104]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0104, Barges Carrying Bulk Hazardous Materials; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before September 26, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0341] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0341], and must be received by September 26, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Barges Carrying Bulk Hazardous Materials.

OMB Control Number: 1625–0104.

Summary: This information is needed to ensure the safe shipment of bulk hazardous liquids in barges. The requirements are necessary to ensure that barges meet safety standards and to ensure that barge's crewmembers have the information necessary to operate barges safely.

Need: 46 U.S.C. 3703 authorizes the Coast Guard to prescribe rules related to the carriage of liquid bulk dangerous cargoes. 46 CFR 151 prescribes rules for barges carrying bulk liquid hazardous materials.

Forms: N/A.

Respondents: Owners and operators of tank barges.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 24,752 hours a year to 27,262 hours, due to an increase in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: July 20, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–15900 Filed 7–25–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP).

DATES: The date of December 15, 2022 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

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 Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Charlotte County, Florida and Incorporated Areas Docket No.: FEMA–B–2074	
City of Punta Gorda	City Hall, 326 West Marion Avenue, Punta Gorda, FL 33950.
Unincorporated Areas of Charlotte County	Charlotte County Building Department, 18400 Murdock Circle, Port Charlotte, FL 33948.
Walton County, Georgia and Incorporated Areas Docket No.: FEMA–B–2152	
City of Good Hope	City Hall, 169 Highway 83, Good Hope, GA 30641.
City of Monroe	City Hall, 215 North Broad Street, Monroe, GA 30655.
City of Social Circle	City Hall, 166 North Cherokee Road, Social Circle, GA 30025.
Unincorporated Areas of Walton County	Walton County Planning and Development Office, 303 South Hammond Drive, Suite 98, Monroe, GA 30655.
Cerro Gordo County, Iowa and Incorporated Areas Docket No.: FEMA–B–2162	
City of Clear Lake	Public Works Office, 1419 2nd Avenue South, Clear Lake, IA 50428.
City of Mason City	City Hall, 10 1st Street Northwest, Mason City, IA 50401.
City of Ventura	City Hall, 101 Sena Street, Ventura, IA 50482.
Unincorporated Areas of Cerro Gordo County	Cerro Gordo County Courthouse, 220 North Washington Avenue, Mason City, Iowa 50401.
Dallas County, Iowa and Incorporated Areas Docket No.: FEMA–B–2165	
City of Adel	City Hall, 301 South 10th Street, Adel, IA 50003.
City of Van Meter	City Hall, 310 Mill Street, Van Meter, IA 50261.
City of Waukee	City Hall, 230 West Hickman Road, Waukee, IA 50263.
Unincorporated Areas of Dallas County	Dallas County Planning and Development Department, 907 Court Street, Adel, IA 50003.
Winnebago County, Iowa and Incorporated Areas Docket No.: FEMA–B–2145	
City of Leland	City Hall, 316 Walnut Street, Leland, IA 50453.
Unincorporated Areas of Winnebago County	Winnebago County Courthouse, 126 South Clark Street, Forest City, IA 50436.
Mackinac County, Michigan (All Jurisdictions) Docket No.: FEMA–B–2128	
City of Mackinac Island	City Hall, 7358 Market Street, Mackinac Island, MI 49757.
City of St. Ignace	City Hall, 396 North State Street, St. Ignace, MI 49781.
Sault Sainte Marie Tribe of the Chippewa Indians	Sault Tribe Administration Building, 523 Ashmun Street, Sault Sainte Marie, MI 49783.
Township of Bois Blanc	Bois Blanc Township Hall, 431 Sioux Avenue, Pointe Aux Pins, MI 49775.
Township of Brevort	Brevort Township Community Center, 4020 Church Road, Moran, MI 49760.
Township of Clark	Clark Township Hall, 207 North Blindline Road, Cedarville, MI 49719.
Township of Garfield	Garfield Township Hall, 6760 State Highway M–117, Engadine, MI 49827.
Township of Hendricks	Hendricks Township Hall, 5115 Hiawatha Trail, Naubinway, MI 49762.
Township of Hudson	Hudson Township Hall, 7961 Church Street, Rexton, MI 49762.
Township of Marquette	Marquette Township Hall, 7177 East James Street, Pickford, MI 49774.
Township of Moran	Moran Township Hall, 1362 West US–2, St. Ignace, MI 49781.
Township of Newton	Newton Township Hall, 6164 South Gould City Road, Gould City, MI 49838.
Township of St. Ignace	Township Hall, 4298 Gorman Road, St. Ignace, MI 49781.

Community	Community map repository address
City of Hopewell, Virginia (Independent City) Docket No.: FEMA–B–2152	
City of Hopewell	City Hall, 300 North Main Street, Hopewell, VA 23860.
City of Petersburg, Virginia (Independent City) Docket No.: FEMA–B–2149	
City of Petersburg	City Hall, 135 North Union Street, Petersburg, VA 23803.

[FR Doc. 2022–15915 Filed 7–25–22; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.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 Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65. The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, 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.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Arizona: Santa Cruz (FEMA Docket No.: B–2220).	Unincorporated areas of Santa Cruz County (21–09–1274P).	The Honorable Manuel Ruiz, Chair, Santa Cruz County Board of Supervisors, 2150 North Congress Drive, Suite 119, Nogales, AZ 85621.	Santa Cruz County Complex, 2150 North Congress Drive, Suite 116, Nogales, AZ 85621.	Jun. 21, 2022	040090
Colorado: Boulder (FEMA Docket No.: B–2226).	City of Boulder (21–08–0987P).	The Honorable Aaron Brockett, Mayor, City of Boulder, 1777 Broadway, Boulder, CO 80306.	City Hall, 1777 Broadway, Boulder, CO 80306.	Jul. 1, 2022	080024
Florida:					
Bay (FEMA Docket No.: B–2231).	City of Lynn Haven (20–04–4506P).	Vickie Gainer, Manager, City of Lynn Haven, 825 Ohio Avenue, Lynn Haven, FL 32444.	Building Department, 817 Ohio Avenue, Lynn Haven, FL 32444.	Jun. 27, 2022	120009
Bay (FEMA Docket No.: B–2231).	City of Panama City (20–04–4506P).	The Honorable Greg Brudnicki, Mayor, City of Panama City, 501 Harrison Avenue, Panama City, FL 32401.	Public Works Department, Engineering Division, 501 Harrison Avenue, Panama City, FL 32401.	Jun. 27, 2022	120012

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Bay (FEMA Docket No.: B–2231).	Unincorporated areas of Bay County (20–04–4506P).	The Honorable Robert Carroll, Chair, Bay County Board of Commissioners, 840 West 11th Street, Panama City, FL 32401.	Bay County Planning and Zoning Department, 840 West 11th Street, Panama City, FL 32401.	Jun. 27, 2022	120004
Bay (FEMA Docket No.: B–2226).	Unincorporated areas of Bay County (21–04–2502P).	The Honorable Robert Carroll, Chair, Bay County Board of Commissioners, 840 West 11th Street, Panama City, FL 32401.	Bay County Planning Department, 840 West 11th Street, Panama City, FL 32401.	Jun. 21, 2022	120004
Charlotte (FEMA Docket No.: B–2220).	Unincorporated areas of Charlotte County (22–04–0620P).	The Honorable Bill Truex, Chair, Charlotte County Board of Commissioners, 18500 Murdock Circle, Suite 536, Port Charlotte, FL 33948.	Charlotte County Community Development Department, 18400 Murdock Circle, Port Charlotte, FL 33948.	Jun. 21, 2022	120061
Lake (FEMA Docket No.: B–2231).	City of Leesburg (21–04–3589P).	Al Minner, Manager, City of Leesburg, P.O. Box 490630, Leesburg, FL 34749.	Planning and Zoning Department, 204 North 5th Street, Leesburg, FL 34748.	Jun. 27, 2022	120136
Lake (FEMA Docket No.: B–2231).	Unincorporated areas of Lake County (21–04–3589P).	Jennifer Barker, Lake County Interim Manager, P.O. Box 7800, Tavares, FL 32778.	Lake County Public Works Department, 323 North Sinclair Avenue, Tavares, FL 32778.	Jun. 27, 2022	120421
Monroe (FEMA Docket No.: B–2226).	City of Marathon (22–04–0625P).	The Honorable John Bartus, Mayor, City of Marathon, 9805 Overseas Highway, Marathon, FL 33050.	Planning Department, 9805 Overseas Highway, Marathon, FL 33050.	Jun. 21, 2022	120681
Georgia:					
Hall (FEMA Docket No.: B–2226).	City of Oakwood (21–04–4607P).	The Honorable Lamar Scroggs, Mayor, City of Oakwood, P.O. Box 99, Oakwood, GA 30566.	Department of Public Works, 4035 Walnut Circle, Oakwood, GA 30566.	Jun. 23, 2022	130334
Hall (FEMA Docket No.: B–2226).	Unincorporated areas of Hall County (21–04–4607P).	Jock Connell, Hall County Administrator, P.O. Drawer 1435, Gainesville, GA 30503.	Hall County Engineering Division, 2875 Browns Bridge Road, Gainesville, GA 30503.	Jun. 23, 2022	130466
Kentucky: Fayette (FEMA Docket No.: B–2226).	Lexington-Fayette Urban County Government (21–04–2906P).	The Honorable Linda Gorton, Mayor, Lexington-Fayette Urban County Government, 200 East Main Street, Lexington, KY 40507.	Engineering Department, 101 East Vine Street, 4th Floor, Lexington, KY 40507.	Jun. 29, 2022	210067
Massachusetts:					
Plymouth (FEMA Docket No.: B–2226).	Town of Marion (21–01–1425P).	The Honorable Norman A. Hills, Chair, Town of Marion Board of Selectmen, 2 Spring Street, Marion, MA 02738.	Building Department, 2 Spring Street, Marion, MA 02738.	Jun. 17, 2022	255213
Plymouth (FEMA Docket No.: B–2226).	Town of Mattapoisett (21–01–1425P).	The Honorable Jordan C. Collyer, Chair, Town of Mattapoisett Board of Selectmen, 16 Main Street, Mattapoisett, MA 02739.	Building Department, 16 Main Street, Mattapoisett, MA 02739.	Jun. 17, 2022	255214
Montana:					
Missoula (FEMA Docket No.: B–2226).	City of Missoula (21–08–0781P).	The Honorable John Engen, Mayor, City of Missoula, 435 Ryman Street, Missoula, MT 59802.	Department of Planning and Grants, 435 Ryman Street, Missoula, MT 59802.	Jun. 27, 2022	300049
Missoula (FEMA Docket No.: B–2226).	Unincorporated areas of Missoula County (21–08–0781P).	The Honorable Juanita Vero, Chair, Missoula County Board of Commissioners, 200 West Broadway Street, Missoula, MT 59802.	Missoula County Community and Planning Services Department, 323 West Alder Street, Missoula, MT 59802.	Jun. 27, 2022	300048
New Mexico:					
San Juan (FEMA Docket No.: B–2231).	City of Aztec (21–06–1857P).	The Honorable Michael A. Padilla, Sr., Mayor, City of Aztec, 201 West Chaco Street, Aztec, NM 87410.	City Hall, 201 West Chaco Street, Aztec, NM 87410.	Jul. 5, 2022	350065
San Juan (FEMA Docket No.: B–2231).	Unincorporated areas of San Juan County (21–06–1857P).	Mike Stark, San Juan County Manager, 100 South Oliver Drive, Aztec, NM 87410.	San Juan County Fire Operations Building, 209 South Oliver Drive, Aztec, NM 87410.	Jul. 5, 2022	350064
North Carolina: Cumberland (FEMA Docket No.: B–2232).	City of Fayetteville (21–04–3782P).	The Honorable Mitch Colvin, Mayor, City of Fayetteville, 433 Hay Street, Fayetteville, NC 28301.	Zoning Department, 433 Hay Street, Fayetteville, NC 28301.	Jul. 27, 2022	370077
North Dakota:					
Cass (FEMA Docket No.: B–2226).	City of Mapleton (21–08–0692P).	The Honorable Andrew Draeger, Mayor, City of Mapleton, 651 2nd Street, Mapleton, ND 58059.	Moore Engineering Inc., 1042 14th Avenue, Suite 101, West Fargo, ND 58076.	Jun. 16, 2022	380023
Cass (FEMA Docket No.: B–2226).	Township of Durbin (21–08–0692P).	The Honorable Keith Gohdes, Chair, Township of Durbin Board of Commissioners, 3747 160th ½ Avenue Southeast, Mapleton, ND 58079.	Township Hall, 3768 157 R Avenue, Southeast, Casselton, ND 58012.	Jun. 16, 2022	380325
Pennsylvania:					
Montgomery (FEMA Docket No.: B–2231).	Municipality of Norristown (21–03–1308P).	Crandall O. Jones, Administrator, Municipality of Norristown, 235 East Airy Street, Norristown, PA 19401.	Municipality Hall, 235 East Airy Street, Norristown, PA 19401.	Jun. 27, 2022	425386
Montgomery (FEMA Docket No.: B–2231).	Township of Upper Merion (21–03–1308P).	Anthony T. Hamaday, Manager, Township of Upper Merion, 175 West Valley Forge Road, King of Prussia, PA 19406.	Township Hall, 175 West Valley Forge Road, King of Prussia, PA 19406.	Jun. 27, 2022	420957
Montgomery (FEMA Docket No.: B–2231).	Township of West Norriton (21–03–1308P).	Jason Bobst, Manager, Township of West Norriton, 1630 West Marshall Street, Jeffersonville, PA 19403.	Township Hall, 1630 West Marshall Street, Jeffersonville, PA 19403.	Jun. 27, 2022	420711
South Carolina:					

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Jasper (FEMA Docket No.: B–2226).	City of Hardeeville (21–04–4372P).	Michael J. Czymbor, Manager, City of Hardeeville, P.O. Box 609, Hardeeville, SC 29927.	City Hall, 205 Main Street, Hardeeville, SC 29927.	Jun. 30, 2022	450113
Jasper (FEMA Docket No.: B–2226).	Unincorporated areas of Jasper County (21–04–4372P).	The Honorable Barbara Clark, Chair, Jasper County Council, 358 3rd Avenue, Ridgeland, SC 29936.	Jasper County Planning and Building Services Department, 358 3rd Avenue, Ridgeland, SC 29936.	Jun. 30, 2022	450112
Texas:					
Bell (FEMA Docket No.: B–2226).	Unincorporated areas of Bell County (21–06–2729P).	The Honorable David Blackburn, Bell County Judge, P.O. Box 768, Belton, TX 76513.	Bell County Engineering Department, 206 North Main Street, Belton, TX 76513.	Jun. 27, 2022	480706
Bexar (FEMA Docket No.: B–2231).	City of San Antonio (21–06–2681P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capitol Improvements Department, Storm Water Division, 114 West Commerce Street, 7th Floor, San Antonio, TX 78205.	Jun. 27, 2022	480045
Brazoria (FEMA Docket No.: B–2220).	City of Sweeny (21–06–0575P).	The Honorable Jeff Farley, Mayor, City of Sweeny, P.O. Box 248, Sweeny, TX 77480.	City Hall, 102 West Ashley Wilson Road, Sweeny, TX 77480.	Jun. 16, 2022	485512
Brazoria (FEMA Docket No.: B–2220).	Unincorporated areas of Brazoria County (21–06–0575P).	The Honorable L.M. ''Matt'' Sebesta, Jr., Brazoria County Judge, 111 East Locust Street, Angleton, TX 77515.	Brazoria County West Annex Building, 451 North Velasco Street, Suite 210, Angleton, TX 77515.	Jun. 16, 2022	485458
Dallas (FEMA Docket No.: B–2231).	City of Dallas (21–06–1960P).	The Honorable Eric Johnson, Mayor, City of Dallas, 1500 Marilla Street, Room 5EN, Dallas, TX 75201.	Oak Cliff Municipal Center, 320 East Jefferson Boulevard, Room 312, Dallas, TX 75203.	Jul. 5, 2022	480171
Montgomery (FEMA Docket No.: B–2231).	City of Conroe (21–06–1436P).	The Honorable Jody Czajkoski, Mayor, City of Conroe, 300 West Davis Street, Conroe, TX 77301.	Engineering Department, 700 Metcalf Street, Conroe, TX 77301.	Jul. 1, 2022	480484
Montgomery (FEMA Docket No.: B–2231).	Unincorporated areas of Montgomery County (21–06–1567P).	The Honorable Mark J. Keough, Montgomery County Judge, 501 North Thompson Street, Suite 401, Conroe, TX 77301.	Montgomery County Engineering Department, 501 North Thompson Street, Suite 103, Conroe, TX 77301.	Jun. 27, 2022	480483
Virginia: Buchanan (FEMA Docket No.: B–2226).	Town of Grundy (21–03–1165P).	Dennis A. Ramey, Manager, Town of Grundy, 1185 Plaza Drive, Grundy, VA 24614.	Department of Public Works, 1185 Plaza Drive, Grundy, VA 24614.	Jun. 17, 2022	510025

[FR Doc. 2022–15916 Filed 7–25–22; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–42]

30-Day Notice of Proposed Information Collection: HUD-Administered Small Cities Program Performance Assessment Report, OMB Control No.: 2506–0020

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* August 25, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.* Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email her at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on May 6, 2022, at 87 FR 27180.

A. Overview of Information Collection

Title of Information Collection: HUD-Administered Small Cities Program Performance Assessment Report.

OMB Approval Number: 2506–0020.

Type of Request: Extension of a currently approved collection.

Form Number: HUD–4052.

Description of the need for the information and proposed use: Section 104(e) of the Housing and Community Development Act (HCDA) of 1974 require that each grantee must submit a performance and evaluation report to HUD. An extension without change of a currently approved collection is requested for the annual performance assessment report, submitted by the grantees in the Small Cities program enabling HUD to track program progress.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD–4052	40	1.0	40	4.0	160	$43.04	$6,886.40

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) If the information will be processed and used in a timely manner;

(3) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(4) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(5) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Data Officer.

[FR Doc. 2022–16007 Filed 7–25–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[223A2100DD/AAKC001030/ A0A501010.999900]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact in the State of Arizona

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This Notice publishes the approval of the Yavapai-Prescott Indian Tribe—State of Arizona Amended and Restated Gaming Compact (Compact) and the Agreement to Amend Compact (Amendment) between the Yavapai-Prescott Indian Tribe (Tribe) and the State of Arizona (State).

DATES: The compact and amendment take effect on July 26, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Yavapai-Prescott Indian Tribe and the State of Arizona agreed to the Compact and then to the Amendment. The Compact permits various types of gaming, including video devices, house banked card games, off-track pari-mutuel wagering, dealer controlled electronic games, sports wagering, fantasy sports contests, and live table games on the Tribe's Indian lands. The Compact includes provisions requiring the Tribe to pay the State from the Tribe's net win in exchange for substantial exclusivity in the State and for regulatory costs. The Compact provides that the Tribe will have the responsibility to administer and enforce regulatory requirements. The Amendment clarifies certain definitions and provisions in the Compact. The Compact and the Amendment are approved.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–16024 Filed 7–25–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–IMR–WUPA–32891; PPIMFLAGS2, PPMPSPD1Z.YM]

Determination of Eligibility for Consideration as Wilderness Areas, Wupatki National Monument, Arizona

AGENCY: National Park Service, Interior

ACTION: Notice of Determination of Wilderness Eligibility for Lands in Wupatki National Monument.

SUMMARY: Pursuant to the Wilderness Act of 1964, and in accordance with National Park Service (NPS) Management Policies (2006), Section 6.2.1, the NPS has completed a Wilderness Eligibility Assessment to determine if lands within Wupatki National Monument (Wupatki or monument) meet criteria indicating eligibility for preservation as wilderness.

ADDRESSES: A map of lands assessed is on file at Wupatki National Monument Headquarters, 6400 U.S. 89, Flagstaff, AZ 86004.

FOR FURTHER INFORMATION CONTACT: Acting Superintendent Kristofer Butcher, Flagstaff Area National Monuments, 6400 U.S. 89, Flagstaff, AZ 86004, Telephone: 928–526–1157 or 205–410–3543, email address: *Kristofer_butcher@nps.gov.*

SUPPLEMENTARY INFORMATION: Wupatki National Monument has determined that a significant portion of the lands within the monument are eligible for wilderness designation. Areas determined to be eligible for wilderness designation total 34,194 acres or 96.5% of Wupatki's total 35,424 acres, with the remaining 1,230 acres or 3.5% of total monument acreage determined not eligible for wilderness designation.

Eligible wilderness areas at Wupatki National Monument are subdivided into the following areas:

Eligible Wilderness Area 1: 6,284 acres. This area contains outstanding grassland resources with some juniper savanna in the eastern portions. The landscape is dominated by basalt mesas and offers prime habitat for pronghorn antelope. The area is largely undeveloped and retains most of its primeval character. This area is managed to protect pronghorn habitat and sensitive cultural resources. The western-most portion of this area is affected by the presence of Highway 89 but is still eligible to be designated as wilderness.

Eligible Wilderness Area 2: 21,168 acres. Almost the entire area is undeveloped, with few signs of people and one rarely used administrative road (Crack-in-Rock Road). This area generally appears to be affected primarily by natural forces. The area offers a variety of habitats including pristine grassland, juniper savanna, and cold desert scrub, and is bisected by a prominent geologic feature known as the Doney monocline. The monocline contains deeply incised washes including Antelope Wash, and outstanding views of the Painted Desert, Little Colorado River valley to the north and east, and the San Francisco Peaks to the south. Spectacular features found in this area include red formations of Moenkopi sandstone and areas such as Deadman Wash, which extends from well south of the monument around the north side of the San Francisco Peaks, all the way to the Little Colorado River.

Eligible Wilderness Area 3: 1,929 acres. This area surrounds Wupatki

National Monument's primary interpretive feature, the Visitor Center, and the housing area. Some development has occurred within this area to support monument operations; however, it is confined to the Wupatki Visitor Center area and on top of the Woodhouse Mesa. One above ground utility line runs to Woodhouse Mesa, however, as the monument strives to become more energy efficient and self-sufficient, it will pursue removing the above ground line. The rest of the area consists of Doney Mountain and Deadman Wash. Although this wilderness area is less than 5,000 acres, this area can be managed as wilderness because the landscape is homogenous with the surrounding eligible wilderness areas but is bisected by the primary road that goes through Wupatki. This area has many locations not affected by modern development and the potential for seclusion exists in this area. The area outside of the administrative zones is undeveloped and is affected primarily by natural forces.

Eligible Wilderness Area 4: 4,813 acres. This area contains outstanding Moenkopi sandstone outcrops and deep washes. The landscape is dominated by basalt mesas and offers prime locations for isolation and quiet. The area is largely undeveloped and retains most of its primeval character except for an interpretive pueblo site with associated parking area and access road (Wukoki Pueblo), a small administrative area used for maintenance activities (New Heiser) and a special use permit residence with associated road access. At the expiration of the special use permit for the residence, the area will be rehabilitated to restore natural conditions.

In accordance with NPS Management Policies (2006), Section 6.2.2, Wupatki National Monument will prepare a wilderness study to determine if any portions of the monument should be recommended for inclusion in the National Wilderness Preservation System as defined in the Wilderness Act of 1964.

Charles F. Sams, III,

Director, National Park Service.

[FR Doc. 2022–15970 Filed 7–25–22; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–718 (Fifth Review)]

Glycine From China; Scheduling of Expedited Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on glycine from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: April 8, 2022.

FOR FURTHER INFORMATION CONTACT: Tyler Berard (202–205–3354), 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 review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On April 8, 2022, the Commission determined that the domestic interested party group response to its notice of institution (87 FR 112, January 3, 2022) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review 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, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the review has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for this review on July 21, 2022. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the review may file written comments with the Secretary on what determinations the Commission should reach in the review. Comments are due on or before July 28, 2022 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by July 28, 2022. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI

[1] A record of the Commissioners' votes is available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the response to its notice of institution filed on behalf of GEO Specialty Chemicals, Inc., a domestic producer of glycine, to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 20, 2022.

Katherine M. Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–15936 Filed 7–25–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1260]

Certain Toner Supply Containers and Components Thereof (II); Notice of Commission Final Determination Finding a Violation of Section 337; Issuance of a General 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 (''Commission'') has found a violation of section 337 of the Tariff Act of 1930, as amended, in this investigation and has issued a general exclusion order (''GEO'') prohibiting the importation of certain infringing toner supply containers and components thereof, as well as cease and desist orders (''CDOs'') against certain defaulting respondents. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: On April 13, 2021, the Commission instituted this investigation based on a complaint filed by Canon Inc. of Tokyo, Japan; Canon U.S.A., Inc. of Melville, New York; and Canon Virginia, Inc. of Newport News, Virginia (collectively, ''Canon''). 86 FR 19287–88 (Apr. 13, 2021). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337) (''section 337''), based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain toner supply containers and components thereof by reason of infringement of certain claims of thirteen patents: U.S. Patent Nos. 10,209,667; 10,289,060; 10,289,061; 10,295,957; 10,488,814; 10,496,032; 10,496,033; 10,514,654; 10,520,881; 10,520,882; 8,565,649 (''the '649 patent''); 9,354,551 (''the '551 patent''); and 9,753,402 (''the '402 patent''). *Id.* at 19287. The complaint further alleges that a domestic industry (''DI'') exists. *Id.*

The Commission instituted two separate investigations based on the complaint and defined the scope of the present investigation as whether there is a violation of section 337 based on the allegations of infringement as to the asserted claims of the '649, '551, and '402 patents (collectively, ''the Asserted Patents'') as to the accused products identified in the notice of investigation (''NOI''). *Id.* The NOI named eleven respondents: (1) Sichuan XingDian Technology Co., Ltd. (''Sichuan Xing Dian'') of Sichuan, China; (2) Sichuan Wiztoner Technology Co., Ltd. (''Sichuan Wiztoner'') of Sichuan, China; (3) Anhuiyatengshangmaoyou xiangongsi (''Yatengshang'') of Ganyuqu, China; (4) ChengDuXiang ChangNanShiYouSheBeiYouXianGong Si (''ChengDuXiang'') of SiChuanSheng, China; (5) Digital Marketing Corporation d/b/a Digital Buyer Marketing Company (''Digital Buyer'') of Los Angeles, California; (6) Do It Wiser, LLC d/b/a Image Toner of Wilmington, Delaware; (7) Hefeierlandianzishangwuyouxian gongsi (''Erlandianzishang'') of Chengdushi, China; (8) MITOCOLOR INC. (''TopInk'') of Rowland Heights, California; (9) Xianshi yanliangqu canqiubaihuodianshanghang of Shanxisheng, China; (10) Zhuhai Henyun Image Co., Ltd. of Zhuhai, China (collectively, the ''Defaulting Respondents''); and (11) Shenzhenshi Keluodeng Kejiyouxiangognsi (''KenoGen'') of Guangdong, China. *Id.* The Office of Unfair Import Investigations (''OUII'') is also named as a party. *Id.* at 19287–88. The Commission's determination in Inv. No. 337–TA–1259 will separately address any violation of section 337 based on infringement of the asserted claims of the remaining patents in Canon's complaint. *See* 86 FR 19284–86 (Apr. 13, 2021).

On May 27, 2021, the Commission granted Canon's motion to amend the complaint and NOI to change the identification of Do It Wiser, LLC d/b/a Image Toner to Do It Wiser, Inc. d/b/a Image Toner (hereinafter, ''Do It Wiser'') and to make related changes in paragraph 31 of the complaint. Order No. 6 (May 17, 2021), *unreviewed by* 86 FR 29806–07 (June 3, 2021).

On September 7, 2021, the Commission terminated the following asserted claims from the investigation based on Canon's withdrawal of the complaint as to those claims: (i) claim 2 of the '649 patent; (ii) claims 2, 3, 6, and 7 of the '551 patent; and (iii) claims 25–27, 39–41, and 46 of the '402 patent. Order No. 10 (Aug. 12, 2021), *unreviewed by* Comm'n Notice (Sept. 7, 2021).

Also on September 7, 2021, the Commission terminated respondent KenoGen from the investigation based on Canon's withdrawal of the complaint as to KenoGen. Order No. 12 (Aug. 13, 2021), *unreviewed by* Comm'n Notice (Sept. 7, 2021). As a result, the ten Defaulting Respondents are the only respondents remaining in this investigation.

On October 29, 2021, the Commission found the Defaulting Respondents in default for failing to respond to the complaint and NOI and failing to show cause why they should not be found in default. Order No. 15 (Sept. 29, 2021), *unreviewed by* Comm'n Notice (Oct. 29, 2021).

On October 1, 2021, Canon filed a motion seeking summary determination that the Defaulting Respondents have violated section 337 and requesting a recommendation that the Commission issue a general exclusion order (''GEO''), issue cease and desist orders (''CDOs'') against certain respondents, and set a one hundred percent (100%) bond for any importations of infringing goods during the period of Presidential review. On October 25, 2021, OUII filed a response supporting Canon's motion and requested remedial relief. No Defaulting Respondent filed a response to Canon's motion.

On February 11, 2022, the presiding Chief Administrative Law Judge (''CALJ'') issued an initial determination (''ID'') granting Canon's motion and finding violations of section 337 by the Defaulting Respondents. Specifically, the ID finds that: (i) the Commission has subject matter, personal, and in rem jurisdiction in this investigation; (ii) Canon has standing to assert the Asserted Patents; (iii) Canon has satisfied the importation requirement as to all Defaulting Respondents; (iv) the accused products practice claims 1, 6, 7, 12, 25, and 26 of the '649 patent, claims 1, 4, and 5 of the '551 patent, and claims 1, 15–18, 32, 36, and 37 of the '402 patent; (v) Canon has satisfied the technical prong of the DI requirement with respect to the Asserted Patents; (vi) Canon has satisfied the economic prong of the DI requirement with respect to the Asserted Patents; and (vii) no claim of the Asserted Patents has been shown invalid. The CALJ's recommended determination on remedy and bonding recommended that the Commission: (i) issue a GEO; (ii) issue CDOs against eight respondents (*i.e.,* Digital Buyer, Do It Wiser, TopInk, Sichuan XingDian, Sichuan Wiztoner, Yatengshang, ChengDuXiang, and Erlandianzishang); and (iii) set a 100 percent bond for any importations of infringing products during the period of Presidential review. No party petitioned for review of the subject ID.

The Commission did not receive any submissions on the public interest from the parties pursuant to Commission Rule 210.50(a)(4) (19 CFR 210.50(a)(4)). The Commission also did not receive any submissions on the public interest from members of the public in response to the Commission's **Federal Register** notice. 87 FR 9379–80 (Feb. 18, 2022).

On March 30, 2022, the Commission determined to review the ID in part. 87 FR 19707–09 (Apr. 5, 2022). Specifically, the Commission determined to review the ID's analysis of the economic prong of DI requirement. *Id.* The Commission further requested briefing on remedy, bonding, and the public interest. *Id.*

On April 13, 2022, Canon and OUII filed their initial written responses to the Commission's request for briefing. On April 10, 2021, Canon and OUII filed reply submissions.

Having reviewed the record of the investigation, including the ID and Canon's and OUII's submissions, the Commission has found a violation of section 337 with respect to Defaulting Respondents. The Commission affirms, with modified analysis, the ID's findings that the economic prong of the DI requirement has been satisfied under section 337(a)(3)(A) and (B). *See* 19 U.S.C. 1337(a)(3)(A), (B). (Commissioner Kearns finds the economic prong satisfied under section 337(a)(3)(A) and takes no position with respect to section 337(a)(3)(B)). (Commissioner Stayin writes separately, but joins the Commission's determination that the economic prong of the DI requirement has been satisfied under section 337(a)(3)(A) and (B).) The Commission also corrects two typographical errors on pages 50 and 58 of the ID, as explained in the Commission's opinion.

Moreover, the Commission finds that the statutory requirements for issuance of a GEO under section 337(g)(2) are met. *See* 19 U.S.C. 1337(g)(2). The Commission also finds it appropriate to issue CDOs against Digital Buyer, Do It Wiser, TopInk, Sichuan XingDian, Sichuan Wiztoner, Yatengshang, ChengDuXiang, and Erlandianzishang. *See* 19 U.S.C. 1337(g)(1). In addition, the Commission finds that the public interest factors do not preclude issuance of the requested relief. *See* 19 U.S.C. 1337(g)(1).

The Commission therefore has determined that the appropriate remedy in this investigation is: (1) a GEO prohibiting the unlicensed entry of certain toner supply containers and components thereof that infringe one or more of claims 1, 6, 7, 12, 25, and 26 of the '649 patent; claims 1, 4, and 5 of the '551 patent; or claims 1, 15, 16, 17, 18, 32, 36, and 37 of the '402 patent; and (2) CDOs against Digital Buyer, Do It Wiser, TopInk, Sichuan XingDian, Sichuan Wiztoner, Yatengshang, ChengDuXiang, and Erlandianzishang. The Commission has also determined that the bond during the period of Presidential review shall be in the amount of 100 percent of the entered value of the Accused Products that are subject to the GEO and CDOs. *See* 19 U.S.C. 1337(j).

The Commission's reasoning in support of its determinations is set forth more fully in its opinion. The Commission's opinion and orders were delivered to the President and to the United States Trade Representative on the day of their issuance. The investigation is terminated.

While temporary remote operating procedures are in place in response to COVID–19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant complete service for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

The Commission vote for this determination took place on July 20, 2022.

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 20, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–15907 Filed 7–25–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Toxic Substances Control Act

On July 19, 2022, the Department of Justice lodged a proposed Consent Decree (the ''Consent Decree'') with the District Court of the Southern District of New York in a lawsuit entitled *United States of America* v. *CISNE NY Construction, Inc., et al.,* Civil Action No. 22–338.

In this action, the United States seeks, as provided under Toxic Substances Control Act (''TSCA''), injunctive relief from Edison Ruilova and CISNE Contracting, Inc., among others, in connection with the defendants' unlawful work practices during renovations governed by an implementing regulation of the TSCA—the Renovation, Repair, and Painting Rule, 40 CFR part 745 (the ''RRP Rule''). The proposed settlement resolves the United States' claims against two of five defendants, requires Edison Ruilova and CISNE Contracting, Inc. to pay $25,000, and imposes injunctive relief. The injunctive relief required of the settling defendants mandates ongoing compliance with the RRP Rule, completion of an RRP Checklist at all worksites, and notification of EPA in advance of projects that implicate the RRP Rule.

The publication of this notice opens the public comment on the proposed settlement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America* v. *CISNE NY Construction, Inc.,* DJ #90–5–2–1–12386. All comments must be submitted no later than 30 days after the

publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	pubcomment-ees.enrd@usdoj.gov.
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the settlement may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the settlement upon written request and payment of reproduction costs. Please email 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 $11.75 (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. 2022–15891 Filed 7–25–22; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reemployment Services and Eligibility Assessment Program

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 25, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The authority to implement this reporting requirement is found in the Social Security Act (SSA) section 303(a)(6), 42 U.S.C. 503(a)(6), which requires that state law include provision for: ''the making of such reports, in such form and containing such information, as the Secretary of Labor may from time-to-time require, and compliance with such provisions as the Secretary of Labor may from time- to-time find necessary to assure the correctness and verification of such reports.'' The Secretary interprets section 303(a)(6) of the SSA to authorize DOL to prescribe standard definitions, methods and procedures, and reporting requirements for the collection of information on benefit payment accuracy and the reemployment of Unemployment Insurance (UI) benefit recipients and to ensure accuracy and verification of these data. This information is collected through Forms ETA 9128 (Reemployment and Eligibility Assessment Workload) and ETA 9129 (Reemployment Services and Eligibility Assessment Outcomes). For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 23, 2021 (86 FR 66593).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Reemployment Services and Eligibility Assessment Program.

OMB Control Number: 1205–0456.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 53.

Total Estimated Number of Responses: 424.

Total Estimated Annual Time Burden: 1,234 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: July 20, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–15967 Filed 7–25–22; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Unemployment Insurance Data Validation Program

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 25, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open

for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Unemployment Insurance Data Validation Program requires States to operate a system for ascertaining the validity of specified unemployment insurance data they submit to the Employment and Training Administration on certain reports they are required to submit monthly or quarterly. Some of these data are used to assess performance, including for the Government Performance and Results Act of 1993 (GPRA), or determine States' grants for UI administration. This information collection is authorized by Section 303(a)(6) of the Social Security Act. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 24, 2022 (87 FR 3588).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Unemployment Insurance Data Validation Program.

OMB Control Number: 1205–0431.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 53.

Total Estimated Number of Responses: 53.

Total Estimated Annual Time Burden: 23,638 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: July 20, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–15968 Filed 7–25–22; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; The Evaluation of the Pathway Home Grant Program

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Chief Evaluation Office (CEO)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 25, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Chief Evaluation Office (CEO) in DOL has commissioned an evaluation of the Pathway Home grant program. The program aims to improve the ability of people in the justice system to find meaningful employment and avoid repeat involvement in the criminal justice system. The Evaluation of the Pathway Home Grant Program (Pathway Home Evaluation) offers a unique opportunity to build knowledge about the implementation and effectiveness of these programs. CEO contracted with Mathematica and its subcontractors, Social Policy Research Associates and the Council of State Governments Justice Center, to conduct an implementation and impact study. This information collection request seeks OMB clearance for new data collection for the Pathway Home Evaluation. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 4, 2021 (86 FR 60917).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–CEO.

Title of Collection: The Evaluation of the Pathway Home Grant Program.

OMB Control Number: 1290–0NEW.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 1,138.

Total Estimated Number of Responses: 1,138.

Total Estimated Annual Time Burden: 512 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior PRA Analyst.

[FR Doc. 2022–15969 Filed 7–25–22; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; The 1,2-Dibromo-3-Chloropropane Standard

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety & Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 25, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The standard requires employers to train workers about the hazards of 1,2-Dibromo-3-Chloropropane (DBCP), to monitor worker exposure, to provide medical surveillance, and maintain accurate records of worker exposure to DBCP. These records will be used by employers, workers, physicians and the Government to ensure that workers are not harmed by exposure to DBCP in the workplace. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 20, 2022 (87 FR 31000).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: The 1,2-Dibromo-3-Chloropropane Standard.

OMB Control Number: 1218–0101.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 1.

Total Estimated Number of Responses: 1.

Total Estimated Annual Time Burden: 1 hour.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior PRA Analyst.

[FR Doc. 2022–16016 Filed 7–25–22; 8:45 am]

BILLING CODE 4510–26–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 22–09]

Notice of Entering Into a Compact With the Democratic Republic of Timor-Leste

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the provisions of the Millennium Challenge Act of 2003, as amended, the Millennium Challenge Corporation (MCC) is publishing a summary of the Millennium Challenge Compact (Compact) between the United States of America, acting through MCC, and the Democratic Republic of Timor-Leste (Timor-Leste). Representatives of MCC and Timor-Leste signed the Compact on July 19, 2022. The complete text of the Compact has been posted at: *https://assets.mcc.gov/content/uploads/compact-timor-leste.pdf.*

(Authority: 22 U.S.C. 7709(b)(3))

Dated: July 21, 2022.

Thomas G. Hohenthaner,

Acting VP/General Counsel and Corporate Secretary.

Summary of Timor-Leste Compact

Overview of the MCC Timor-Leste Compact

MCC's five-year Compact with the Democratic Republic of Timor-Leste in the amount of $420 million aims to reduce poverty through economic growth. The Compact seeks to assist Timor-Leste in addressing the human capital constraint to economic growth through two primary projects: the Water, Sanitation, and Drainage (''WSD'') Project and the Teaching and Leading the Next generation of Timorese (''TALENT'') Project.

Project Summaries

The projects and activities to be completed are:

1. Water, Sanitation, and Drainage Project

The primary objective of the WSD Project is to reduce fecal pathogens in piped and stored drinking water and groundwater. The project aims to mitigate exposure to sanitary waste and pathogens in water, households, and the environment through investments in infrastructure, policy and institutional reform, and social and behavior change. The project will focus its interventions in the capital city of Dili and four nearby municipalities (Aileu, Ermera, Liquica, and Manatuto). Specifically, the WSD Project will support the following activities:

- *Activity 1: Water Disinfection.* This activity will supply disinfected water to Dili and the four municipalities of Timor-Leste through the design and construction of an onsite sodium hypochlorite generation plant.
- *Activity 2: Sanitation.* This activity includes the design and construction of a new wastewater treatment plant, an ocean outfall, wastewater collection systems, and wastewater connections to households and businesses.

• *Activity 3: Associated Drainage.* This activity supports the implementation of the sanitary sewer system described in the Sanitation Activity through the construction of in-street drainage infrastructure in areas where conflicts with sewer lines would otherwise occur.

• *Activity 4: Institutional Reform.* To ensure long-term sustainability of the WSD Project's infrastructure investments, this activity will support the capacity building and institutional development of Timor-Leste's independent public water utility with a focus on strengthening asset management expertise and operations and maintenance capacity. The activity will further promote sustainability through targeted assistance to Timor-Leste's independent water regulator to develop and implement regulations and public awareness around sanitation and disinfection.

• *Activity 5: Household Water and Hygiene.* This social and behavior change activity includes interventions to increase household and community awareness of the benefits of, and support for, the construction and maintenance of household sanitation units as well as the adoption and maintenance of key behaviors to secure sustained community buy-in for household sanitation infrastructure

2. Teaching and Leading the Next Generation of Timorese Project

The primary objective of the TALENT Project is to improve student learning outcomes. To achieve this objective, the project will invest in teacher and school leader education and training, which are critical to improving student learning. The project will establish the Center of Excellence and improve the pedagogical and leadership skills of existing and future secondary school teachers and leaders through the development and deployment of targeted trainings. Future teachers and a subset of existing teachers will receive professional certification through the Center of Excellence during the life of the Compact. Ultimately, it is expected that all secondary teachers will be required to have Center of Excellence certification in order to be eligible for employment in a government secondary school in Timor-Leste. The project will employ a gender-responsive approach in all activities and place a concerted focus on increasing the number of women as teachers and school leaders in secondary schools through a dedicated sub-activity. Specifically, the TALENT Project will support the following activities:

• *Activity 1: Center of Excellence.* This activity will establish a new autonomous institution in Timor-Leste to provide professional training and certification to future secondary teachers entering the workforce, as well as training and certification of a portion of current secondary teachers.

• *Activity 2: Teacher Training.* This activity involves the development of curriculum, materials, and faculty to train current and future teachers to improve their pedagogical skills that lead to improvements in numeracy, literacy, and soft skills. It also includes the professional certification of all newly trained secondary teachers and a subset of current teachers.

• *Activity 3: School Leadership Training.* This activity will support the training of school leaders to create effective schools through strong school leadership, both in school management and in terms of instructional leadership. It includes the development of curriculum and training materials and the delivery of trainings to current and future school leaders. Training will focus on competencies in school leadership, including gender and social inclusion and information communications technology in education.

• *Activity 4: Ensuring Excellence.* This activity ensures accessibility and quality of all activities carried out under the Center of Excellence. It includes support for quality assurance and monitoring, information and communication technology, and language needs, as well as a specific sub-activity focused on increasing the number of women in teaching and leadership positions in secondary schools.

Compact Budget

The Compact budget is up to $484,000,000, which includes up to $420,000,000 funded by MCC and a contribution from Timor-Leste of $64,000,000.

TABLE 1—TIMOR-LESTE COMPACT BUDGET

Project/activity	Budget (US$)
Water, Sanitation, and Drainage Project	308,205,050
Activity 1: Water Disinfection	8,270,509
Activity 2: Sanitation	278,846,498
Activity 3: Associated Drainage	8,938,044
Activity 4: Institutional Reform	6,950,000
Activity 5: Household Water and Hygiene	5,200,000
Teaching and Leading the Next generation of Timorese Project	40,190,538
Activity 1: Center of Excellence	14,599,454
Activity 2: Teacher Training	14,664,142
Activity 3: School Leadership Training	5,039,535
Activity 4: Ensuring Excellence	5,887,407
Monitoring and Evaluation	6,800,000
Program Administration	64,804,412
Total MCC Funding	420,000,000
Total Government Contribution	64,000,000
Total Program	484,000,000

[FR Doc. 2022–16020 Filed 7–25–22; 8:45 am]

BILLING CODE 9211–03–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) Committee on Oversight hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Friday, July 29, 2022, from 1:00–2:00 p.m. EDT.

PLACE: This meeting will be held by video conference through the National Science Foundation.

STATUS: Open.

MATTERS TO BE CONSIDERED: The agenda of the teleconference is: Committee Chair's opening remarks, including review of pillars for action in the 2022–2024 term; discussion of demographic data collection; Office of the Inspector General report; Chief Financial Officer report; and Committee Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: (Chris Blair, *cblair@nsf.gov*), 703/292–7000. Members of the public can observe this meeting through a You Tube livestream. Access the livestream at *https://youtu.be/dJFgYVVao2I.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–16078 Filed 7–22–22; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register**, and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAmain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Comments: Comments regarding (a) whether the proposed collection of information is necessary for the proper performance of the functions of the NSF, including whether the information shall have practical utility; (b) the accuracy of the NSF's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, use, and clarity of the information on respondents; 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 should be addressed to the points of contact in the **FOR FURTHER INFORMATION CONTACT** section.

Copies of the submission may be obtained by calling 703–292–7556. NSF 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.

SUPPLEMENTARY INFORMATION:

Title of Collection: NCSES Generic Clearance for Improvement Projects.

OMB Number: 3145–0174.

Abstract: Established within the National Science Foundation by the America COMPETES Reauthorization Act of 2010 § 505, codified in the National Science Foundation Act of 1950, as amended, the National Center for Science and Engineering Statistics (NCSES)—one of 13 principal federal statistical agencies—serves as a central Federal clearinghouse for the collection, interpretation, analysis, and dissemination of objective data on science, engineering, technology, research and development for use by practitioners, researchers, policymakers, and the public. NCSES conducts about a dozen nationally representative surveys to obtain the data for these purposes. The Generic Clearance will be used to ensure that the highest quality data are obtained from these surveys. State of the art methodology will be used to develop, evaluate, and test questionnaires and survey concepts as well as to research and improve survey and statistical methodologies. This may include field or pilot tests of questions for future large-scale surveys, as needed. The Generic Clearance will also be used to test and evaluate data dissemination tools and methods in an effort to improve access for data users.

Use of the Information: The purpose of these studies is to use the latest and most appropriate methodology to improve NCSES surveys, evaluate new data collection efforts, and evaluate data dissemination tools and mechanisms. Methodological findings may be presented externally. Improved NCSES surveys, data collections, and data dissemination will help policymakers in decisions on research and development funding, graduate education, and the scientific and engineering workforce, as well as contributing to reduced survey costs.

Expected Respondents: The respondents will be from industry, academia, nonprofit organizations, members of the public, and State, local, and Federal governments. Respondents will be either individuals or institutions, depending on the topic under investigation. NCSES expects to use both qualitative and quantitative procedures, in various modes (*e.g.,* in-person, telephone, web). Up to 28,515 respondents will be contacted across all projects. No respondent will be contacted more than twice in one year under this generic clearance. Every effort will be made to use technology to limit the burden on respondents from small entities.

Estimate of Burden: NCSES estimates that a total reporting and recordkeeping burden of 11,500 hours will result from activities to improve its survey collections and data dissemination tools. The calculation is shown in Table 1.

TABLE 1—POTENTIAL SURVEYS FOR IMPROVEMENT PROJECTS, WITH THE NUMBER OF RESPONDENTS AND BURDEN HOURS

Survey or information collection	2022–25 number of respondents	2022–25 number of hours
Survey of Doctorate Recipients	5000	1100
Survey of Earned Doctorates	2500	945
National Training, Education, and Workforce Survey	660	400
Other surveys of the science and engineering workforce	1250	550
Higher Education Research & Development Survey	450	350
Federally Funded Research & Development Centers (FFRDC) Survey	80	100
State Government Research & Development Survey	150	225
Survey of Nonprofit Research Activities	200	200
Business Enterprise Research & Development Survey	50	150
Survey of Scientific & Engineering Facilities	300	200
Public Perceptions of Science	1100	180
Data dissemination tools and mechanisms	3100	800
Projects conducted under the NCSES Broad Agency Announcement (BAA)	3675	3300
Other surveys and projects not specified	10000	3000
Total	28515	11500

Dated: July 20, 2022.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2022–15945 Filed 7–25–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of July 25, August 1, 8, 15, 22, 29, 2022. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Betty.Thweatt@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of July 25, 2022

There are no meetings scheduled for the week of July 25, 2022.

Week of August 1, 2022—Tentative

There are no meetings scheduled for the week of August 1, 2022.

Week of August 8, 2022—Tentative

There are no meetings scheduled for the week of August 8, 2022.

Week of August 15, 2022—Tentative

There are no meetings scheduled for the week of August 15, 2022.

Week of August 22, 2022—Tentative

There are no meetings scheduled for the week of August 22, 2022.

Week of August 29, 2022—Tentative

There are no meetings scheduled for the week of August 29, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: July 21, 2022.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2022–16052 Filed 7–22–22; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–250 and 50–251; NRC–2018–0074]

Florida Power & Light Company; Turkey Point Nuclear Generating Unit Nos. 3 and 4

AGENCY: Nuclear Regulatory Commission.

ACTION: Subsequent license renewal environmental report supplement; receipt.

SUMMARY: In response to the U.S. Nuclear Regulatory Commission's (NRC) Memorandum and Order, CLI–22–03 (February 24, 2022), the NRC received Environmental Report, Supplement 2, related to the subsequent renewal of Renewed Facility Operating License Nos. DPR–31 and DPR–41, which authorize Florida Power & Light Company (FPL, the applicant) to operate Turkey Point Nuclear Generating (Turkey Point) Unit Nos. 3 and 4. The Environmental Report, Supplement 2, addresses certain environmental impacts of operating Turkey Point for an additional period of 20 years beyond those dates. The NRC is currently reviewing the acceptability of the tendered Environmental Report, Supplement 2, for docketing.

DATES: The subsequent license renewal submittal referenced in this document was available on June 21, 2022.

ADDRESSES: Please refer to Docket ID NRC–2018–0074 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 Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0074. Address questions about Docket IDs to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tam Tran, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3617, email: *Tam.Tran@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has received an Environmental Report, Supplement 2, (ML22160A301) from Florida Power & Light Company, dated June 9, 2022, related to the subsequent renewal of the operating licenses for Turkey Point. The current subsequently renewed operating licenses for Turkey Point Unit Nos. 3 and 4 expire on July 19, 2032, and April 10, 2033, respectively. The Turkey Point units are Pressurized Water Reactors located in Homestead, Miami-Dade County, Florida. The acceptability for docketing of the tendered supplement to the Environmental Report will be the subject of subsequent **Federal Register** notices. A copy of the subsequent license renewal Environmental Report, Supplement 2, for Turkey Point, is also available for inspection near the site, at the Naranja Branch Library, 14850 SW 280 Street, Homestead, Florida 33032.

Dated: July 20, 2022.

For the Nuclear Regulatory Commission.

John M. Moses,

Deputy Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Materials, Safety and Safeguards.

[FR Doc. 2022–15902 Filed 7–25–22; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: U.S. Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This notice identifies Schedule A, B, and C appointing authorities applicable to a single agency that were established or revoked from August 1, 2019 to August 31, 2019.

FOR FURTHER INFORMATION CONTACT: Julia Alford, Senior Executive Resources Services, Senior Executive Services and Performance Management, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 213.103, Schedule A, B, and C appointing authorities available for use by all agencies are codified in the Code of Federal Regulations (CFR). Schedule A, B, and C appointing authorities applicable to a single agency are not codified in the CFR, but the Office of Personnel Management (OPM) publishes a notice of agency-specific authorities established or revoked each month in the **Federal Register** at *www.gpo.gov/fdsys/.* OPM also publishes an annual notice of the consolidated listing of all Schedule A, B, and C appointing authorities, current as of June 30, in the **Federal Register**.

Schedule A

No Schedule A Authorities to report during August 2019.

Schedule B

No Schedule B Authorities to report during August 2019.

Schedule C

The following Schedule C appointing authorities were approved during August 2019.

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF AGRICULTURE	Office of the Under Secretary for Rural Development.	Confidential Assistant	DA190188	08/16/2019
	Office of the Secretary	Deputy Director of Scheduling	DA190186	08/16/2019
		Staff Assistant	DA190192	08/23/2019
		Director of Operations	DA190195	08/26/2019
		Deputy Director of Advance	DA190193	08/27/2019
DEPARTMENT OF COMMERCE	Office of the Director General of the United States and Foreign Commercial Service and Assistant Secretary for Global Markets.	Senior Advisor	DC190143	08/15/2019
	Immediate Office	Special Advisor	DC190124	08/08/2019
	Office of Advance, Scheduling and Protocol.	Special Assistant	DC190132	08/06/2019
		Advance Specialist	DC190134	08/06/2019
	Office of the Under Secretary	Deputy Director of Public Affairs	DC190117	08/06/2019
		Policy Advisor	DC190142	08/13/2019
	Office of Executive Secretariat	Confidential Assistant	DC190135	08/16/2019
DEPARTMENT OF DEFENSE	Office of the Secretary	Special Assistant	DD190168	08/06/2019
	Office of the Secretary of Defense	Speechwriter	DD190154	08/29/2019
DEPARTMENT OF EDUCATION	Office of the General Counsel	Attorney Adviser	DB190118	08/22/2019
DEPARTMENT OF ENERGY	Office of the Assistant Secretary for Congressional and Intergovernmental Affairs.	Associate Deputy Assistant Secretary for Senate Affairs.	DE190163	08/05/2019
		Associate Deputy Assistant Secretary for House Affairs.	DE190164	08/05/2019

Agency name	Organization name	Position title	Authorization No.	Effective date
		Director of Intergovernmental and External Affairs.	DE190168	08/05/2019
	Office of the Assistant Secretary for Electricity Delivery and Energy Reliability.	Special Assistant	DE190179	08/29/2019
	Office of the Assistant Secretary for Energy Efficiency and Renewable Energy.	Special Advisor	DE190178	08/29/2019
	Office of the Assistant Secretary for Environmental Management.	Special Assistant	DE190188	08/29/2019
	Office of the Assistant Secretary for International Affairs.	Senior Advisor	DE190173	08/21/2019
	Loan Programs Office	Senior Advisor	DE190145	08/07/2019
	Office of Cybersecurity, Energy Security and Emergency Response.	Senior Advisor	DE190161	08/05/2019
	Office of General Counsel	Attorney-Advisor	DE190159	08/01/2019
	Office of Management	Special Assistant (2)	DE190169	08/07/2019
			DE190174	08/21/2019
	Office of Policy	Senior Advisor	DE190156	08/05/2019
	Office of Public Affairs	Deputy Director, Office of Public Affairs (2).	DE190170	08/13/2019
			DE190177	08/29/2019
		Special Assistant	DE190175	08/21/2019
		Writer-Editor	DE190162	08/05/2019
	Office of Science	Special Advisor	DE190160	08/02/2019
	Office of Technology Transition	Special Advisor	DE190180	08/29/2019
	Office of the Deputy Secretary	Senior Advisor (2)	DE190183	08/28/2019
			DE190184	08/28/2019
	Office of the Secretary	Senior Advisor for International Affairs.	DE190181	08/26/2019
	Office of the Under Secretary for Science.	Special Advisor	DE190167	08/05/2019
	Office of the Under Secretary of Energy.	Scheduler	DE190176	08/21/2019
		Special Advisor	DE190190	08/28/2019
ENVIRONMENTAL PROTECTION AGENCY.	Office of Public Affairs	Senior Advisor for Strategic Communications and Policy.	EP190120	08/13/2019
		Special Assistant for Digital Media	EP190124	08/26/2019
	Office of Public Engagement and Environmental Education.	Special Assistant	EP190109	08/06/2019
	Office of Public Engagement and Environmental Education.	Special Advisor for Public Engagement.	EP190114	08/06/2019
	Office of the Assistant Administrator for Air and Radiation.	Senior Policy Advisor for the Office of Air and Radiation.	EP190127	08/28/2019
	Office of the Assistant Administrator for Chemical Safety and Pollution Prevention.	Special Advisor	EP190113	08/01/2019
	Office of the Assistant Administrator for Water.	Attorney-Advisor (General)	EP190121	08/19/2019
	Office of the Chief Financial Officer	Senior Advisor for Budget and Accountability.	EP190123	08/29/2019
GENERAL SERVICES ADMINISTRATION.	Office of the Administrator	White House Liaison and Senior Advisor.	GS190038	08/19/2019
DEPARTMENT OF HEALTH AND HUMAN SERVICES.	Centers for Medicare and Medicaid Services.	Advisor for Medicare	DH190216	08/06/2019
	Office for Civil Rights	Special Advisor for Civil Rights	DH190238	08/20/2019
	Office of Communications	Speechwriter	DH190232	08/13/2019
	Office of Intergovernmental and External Affairs.	Special Assistant	DH190244	08/29/2019
	Office of the Assistant Secretary for Health.	Director of External Affairs	DH190218	08/06/2019
		Chief of Staff	DH190235	08/27/2019
	Office of the Assistant Secretary for Legislation.	Chief of Staff	DH190227	08/21/2019
		Special Assistant	DH190228	08/21/2019
	Office of the Assistant Secretary for Public Affairs.	Press Secretary	DH190223	08/13/2019
		Director, Speechwriting and Editorial Services.	DH190246	08/27/2019
	Office of the Secretary	Briefing Book Coordinator	DH190233	08/13/2019
DEPARTMENT OF HOMELAND SECURITY.	Office of the Assistant Secretary for Public Affairs.	Director of Strategic Outreach and Engagement.	DM190267	08/13/2019
	Office of the United States Citizenship and Immigration Services.	Senior Advisor	DM190275	08/21/2019
		Deputy Chief of Staff	DM190276	08/21/2019
	Office of the Chief of Staff	Senior Advisor	DM190279	08/27/2019
	Office of the United States Customs and Border Protection.	Policy Analyst	DM190280	08/27/2019

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.	Office of the Administration	Senior Advisor	DU190108	08/08/2019
	Office of Congressional and Intergovernmental Relations.	Congressional Liaison	DU190109	08/13/2019
	Office of Public Affairs	Deputy Assistant Secretary for Strategic Communication.	DU190111	08/21/2019
DEPARTMENT OF JUSTICE	Office of Public Affairs	Senior Advisor for Strategic Communications and Chief Speechwriter.	DJ190185	08/08/2019
DEPARTMENT OF LABOR	Office of Employee Benefits Security Administration.	Chief of Staff	DL190156	08/16/2019
	Office of Employment and Training Administration.	Senior Policy Advisor	DL190146	08/06/2019
	Office of Mine Safety and Health Administration.	Senior Policy Advisor	DL190145	08/19/2019
	Office of Congressional and Intergovernmental Affairs.	Senior Legislative Officer	DL190143	08/06/2019
	Office of Federal Contract Compliance Programs.	Senior Policy Advisor	DL190149	08/06/2019
	Office of Public Affairs	Press Secretary	DL190147	08/06/2019
	Office of the Assistant Secretary for Administration and Management.	Special Assistant	DL190068	08/15/2019
	Office of the Assistant Secretary for Policy.	Deputy Chief Economist	DL190162	08/22/2019
	Office of the Secretary	Senior Policy Advisor	DL190144	08/06/2019
		Director, Office of Faith-Based and Community Initiatives.	DL190166	08/27/2019
	Office of the Solicitor	Senior Counsel (2)	DL190141	08/01/2019
			DL190160	08/22/2019
	Office of Veterans Employment and Training Service.	Senior Policy Advisor	DL190142	08/06/2019
	Office of the Board	Senior Policy Advisor	CU190002	08/12/2019
NATIONAL CREDIT UNION ADMINISTRATION.	National Credit Union Administration.	Staff Assistant	CU190005	08/12/2019
OFFICE OF MANAGEMENT AND BUDGET.	Office of the General Counsel\	Special Counsel	BO190039	08/06/2019
	Office of Legislative Affairs	Deputy for Legislative Affairs (House).	BO190036	08/05/2019
	Office of the National Security Programs.	Special Assistant	BO190044	08/29/2019
	Office of Information and Regulatory Affairs.	Counselor	BO190037	08/20/2019
	Office of the Director	Special Assistant	BO190038	08/02/2019
		Senior Advisor for Management	BO190045	08/29/2019
OFFICE OF PERSONNEL MANAGEMENT.	Office of Communications	Public Affairs Specialist	PM190053	08/28/2019
SECURITIES AND EXCHANGE COMMISSION.	Office of the Chairman	Confidential Assistant	SE190010	08/06/2019
SMALL BUSINESS ADMINISTRATION.	Office of Communications and Public Liaison.	Senior Advisor	SB190029	08/08/2019
SOCIAL SECURITY ADMINISTRATION.	Office of Information Security	Program Analyst	SZ190003	08/07/2019
DEPARTMENT OF STATE	Bureau of European and Eurasian Affairs.	Strategic Advisor	DS190130	08/26/2019
	Bureau of Legislative Affairs	Special Advisor	DS190131	08/26/2019
DEPARTMENT OF TRANSPORTATION.	Office of the Executive Secretariat	Deputy Director	DT190119	08/28/2019
	Office of the Assistant Secretary for Transportation Policy.	Senior Director of Public Liaison	DT190120	08/28/2019
	Office of the Secretary	Senior Advisor	DT190123	08/28/2019
DEPARTMENT OF THE TREASURY.	Office of the Assistant Secretary (Public Affairs).	Senior Advisor	DY190100	08/21/2019
		Confidential Assistant	DY190101	08/26/2019
	Office of the Under Secretary for International Affairs.	Special Assistant	DY190102	08/26/2019
UNITED STATES INTERNATIONAL TRADE COMMISSION.	Office of the Chairman	Confidential Assistant	TC190006	08/06/2019
	Office of Commissioner Johanson	Staff Assistant	TC190005	08/07/2019

The following Schedule C appointing authorities were revoked during August 2019.

Agency name	Organization name	Position title	Request No.	Date vacated
COMMODITY FUTURES TRADING COMMISSION.	Division of Enforcement	Director, Division of Enforcement	CT170005	08/17/2019
DEPARTMENT OF AGRICULTURE	Office of the Assistant Secretary for Congressional Relations.	Policy and Congressional Advisor	DA180250	08/03/2019
		Staff Assistant	DA180255	08/03/2019
	Office of the Secretary	Special Assistant	DA180258	08/19/2019
		Advanced Lead	DA190019	08/17/2019
	Office of the Under Secretary for Rural Development.	Confidential Assistant	DA180224	08/17/2019
	Rural Housing Service	State Director—Louisiana	DA180126	08/31/2019
DEPARTMENT OF COMMERCE	Office of the Assistant Secretary Legislative and Intergovernmental Affairs.	Intergovernmental Affairs Specialist	DC180151	08/03/2019
	Office of the Director General of the United States and Foreign Commercial Service and Assistant Secretary for Global Markets.	Senior Advisor for China	DC180063	08/06/2019
	Office of International Trade Administration.	Press Secretary and Speechwriter	DC180206	08/17/2019
		Special Assistant to the Under Secretary.	DC180142	08/17/2019
	Office of the Chief of Staff	Special Assistant	DC190056	08/17/2019
	Office of the Under Secretary for Economic Affairs.	Special Advisor	DC190023	08/17/2019
	Office of Advance, Scheduling and Protocol.	Scheduling Assistant	DC180081	08/17/2019
	Office of the Under Secretary	Special Assistant	DC180168	08/30/2019
DEPARTMENT OF DEFENSE	Office of the Assistant Secretary of Defense (Legislative Affairs).	Special Assistant to the Assistant Secretary of Defense (Legislative Affairs).	DD180117	08/31/2019
	Washington Headquarters Services	Defense Fellow	DD180125	08/31/2019
	Office of the Under Secretary of Defense (Personnel and Readiness).	Special Assistant	DD180133	08/31/2019
	Office of the Under Secretary of Defense (Policy).	Special Assistant	DD180098	08/31/2019
DEPARTMENT OF EDUCATION	Office of Communications and Outreach.	Confidential Assistant (2)	DB190092	08/02/2019
			DB190055	08/09/2019
	Office of Planning, Evaluation and Policy Development.	Confidential Assistant	DB190008	08/31/2019
	Office of the General Counsel	Attorney Advisor	DB190047	08/31/2019
DEPARTMENT OF ENERGY	Office of the General Counsel	Attorney-Advisor (General)	DE180114	08/03/2019
	Office of the Secretary	Policy Advisor and Special Assistant to the Deputy Chiefs of Staff.	DE170163	08/03/2019
	Office of the Assistant Secretary for International Affairs.	Special Advisor	DE190147	08/31/2019
DEPARTMENT OF HEALTH AND HUMAN SERVICES.	Office of the Assistant Secretary for Public Affairs.	Press Assistant	DH180157	08/03/2019
	Office of the Assistant Secretary for Public Affairs.	Director, Speechwriting and Editorial Services.	DH180153	08/22/2019
	Office of the Secretary	Advisor to the Secretary for Value-Based Reform.	DH180246	08/09/2019
		Special Assistant	DH190024	08/03/2019
	Office of the Assistant Secretary for Health.	Chief of Staff	DH180212	08/08/2019
		Deputy Chief of Staff	DH180249	08/31/2019
		Executive Director, President's Council on Sports, Fitness and Nutrition.	DH180057	08/08/2019
	Office of Intergovernmental and External Affairs.	Senior Advisor	DH190025	08/17/2019
	Office of the Administration for Children and Families.	Communications Director	DH190203	08/23/2019
		Advisor	DH180145	08/30/2019
	Office of Global Affairs	Advisor	DH170113	08/31/2019
	Office of the Assistant Secretary for Legislation.	Policy Advisor	DH180220	08/31/2019
DEPARTMENT OF HOMELAND SECURITY.	Office of the General Counsel	Oversight Counsel	DM190046	08/24/2019
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.	Office of Housing	Advisor	DU180050	08/04/2019
	Office of Public and Indian Housing	Policy Advisor	DU180107	08/17/2019
		Special Advisor	DU170055	08/18/2019
		Senior Advisor for Single Family Housing.	DU180087	08/31/2019
	Office of the Administration	Director of Scheduling and Advance.	DU180099	08/03/2019
		Special Assistant	DU180106	08/17/2019
	Office of the General Counsel	Senior Counsel	DU190032	08/15/2019

Agency name	Organization name	Position title	Request No.	Date vacated
DEPARTMENT OF JUSTICE	Office of Legislative Affairs	Attorney Advisor	DJ180129	08/24/2019
DEPARTMENT OF STATE	Office of Policy Planning	Senior Advisor	DS180062	08/30/2019
DEPARTMENT OF THE INTERIOR	Secretary's Immediate Office	Senior Advisor to the Secretary	DI180072	08/31/2019
DEPARTMENT OF THE TREASURY.	Office of the Assistant Secretary (Public Affairs).	Public Affairs Specialist	DY180061	08/02/2019
DEPARTMENT OF TRANSPORTATION.	Office of the Assistant Secretary for Transportation Policy.	Director of Public Engagement	DT190005	08/31/2019
	Office of the Executive Secretariat	Deputy Director	DT180070	08/23/2019
		Special Assistant to the Director	DT190054	08/31/2019
	Office of the Secretary	Senior Advisor to the Secretary	DT170051	08/17/2019
		Special Assistant for Scheduling and Advance.	DT180058	08/31/2019
ENVIRONMENTAL PROTECTION AGENCY.	Office of Public Affairs	Public Affairs Specialist	EP190019	08/03/2019
	Office of Public Engagement and Environmental Education.	Special Advisor for Agriculture Outreach.	EP190077	08/17/2019
	Office of the Administrator	Special Assistant	EP180003	08/03/2019
		Senior Advisor for Health and Human Safety.	EP190016	08/09/2019
		Deputy White House Liaison	EP180096	08/17/2019
	Office of the Assistant Administrator for Air and Radiation.	Policy Advisor	EP180095	08/31/2019
	Office of the Assistant Administrator for Chemical Safety and Pollution Prevention.	Environmental Engineer	EP180090	08/17/2019
	Office of the Assistant Administrator for Research and Development.	Confidential Assistant	EP180082	08/03/2019
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION.	Office of Legislative and Intergovernmental Affairs.	Legislative Affairs Specialist	NN190002	08/31/2019
OFFICE OF MANAGEMENT AND BUDGET.	Office of Communications	Deputy Press Secretary	BO180024	08/31/2019
SECURITIES AND EXCHANGE COMMISSION.	Office of the Chairman	Confidential Assistant	SE190002	08/16/2019
SMALL BUSINESS ADMINISTRATION.	Office of Field Operations	Regional Administrator, Region III	SB170065	08/31/2019

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2022–15896 Filed 7–25–22; 8:45 am]

BILLING CODE 6325–39–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This notice identifies Schedule A, B, and C appointing authorities applicable to a single agency that were established or revoked from November 1, 2021 to November 30, 2021.

FOR FURTHER INFORMATION CONTACT: Julia Alford, Senior Executive Resources Services, Senior Executive Services and Performance Management, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 213.103, Schedule A, B, and C appointing authorities available for use by all agencies are codified in the Code of Federal Regulations (CFR). Schedule A, B, and C appointing authorities applicable to a single agency are not codified in the CFR, but the Office of Personnel Management (OPM) publishes a notice of agency-specific authorities established or revoked each month in the **Federal Register** at *www.gpo.gov/fdsys/.* OPM also publishes an annual notice of the consolidated listing of all Schedule A, B, and C appointing authorities, current as of June 30, in the **Federal Register**.

Schedule A

No Schedule A Authorities to report during November 2021.

Schedule B

No Schedule B Authorities to report during November 2021.

Schedule C

The following Schedule C appointing authorities were approved during November 2021.

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF AGRICULTURE	Office of Under Secretary for Natural Resources and Environment.	Confidential Assistant	DA220015	11/05/2021
	Farm Service Agency	Confidential Assistant	DA220016	11/05/2021
		State Executive Director—Alabama	DA220020	11/18/2021
		State Executive Director—Colorado	DA220023	11/29/2021
		State Executive Director—Delaware.	DA220022	11/18/2021
		State Executive Director—Iowa	DA220014	11/18/2021

Agency name	Organization name	Position title	Authorization No.	Effective date
	National Institute of Food and Agriculture.	Senior Advisor	DA220018	11/05/2021
	Office of the General Counsel	Confidential Assistant	DA220027	11/30/2021
	Office of Rural Development	State Director—Iowa	DA220013	11/18/2021
DEPARTMENT OF COMMERCE	Bureau of Industry and Security	Congressional Affairs Specialist	DC220011	11/05/2021
	Bureau of the Census	Chief of Congressional Affairs	DC220009	11/05/2021
	National Oceanic and Atmospheric Administration.	Special Assistant	DC210123	11/05/2021
	National Telecommunications and Information Administration.	Senior Advisor	DC220010	11/05/2021
	Office of Legislative and Intergovernmental Affairs.	Director for Oversight	DC220008	11/05/2021
	Office of Policy and Strategic Planning.	Senior Policy Advisor	DC220007	11/05/2021
DEPARTMENT OF DEFENSE	Office of the Assistant Secretary of Defense (Legislative Affairs).	Special Assistant	DD220015	11/15/2021
	Office of the Director (Cost Assessment and Program Evaluation).	Special Assistant	DD220017	11/17/2021
	Washington Headquarters Services	Defense Fellow (4)	DD220013	11/11/2021
			DD220011	11/17/2021
			DD220014	11/17/2021
			DD220016	11/17/2021
DEPARTMENT OF THE AIR FORCE.	Office of Assistant Secretary Air Force for Financial Management and Comptroller.	Special Assistant	DF220003	11/19/2021
DEPARTMENT OF EDUCATION	Office of the Secretary	Director, Strategic Partnerships	DB220003	11/09/2021
	Office for Civil Rights	Deputy Assistant Secretary for Legal Affairs.	DB220002	11/11/2021
DEPARTMENT OF ENERGY	Office of Management	Director of Advance	DE220003	11/05/2021
	Office of Policy	Chief of Staff	DE220005	11/05/2021
GENERAL SERVICES ADMINISTRATION.	Office of Congressional and Intergovernmental Affairs.	Deputy Associate Administrator for Policy (2).	GS220004	11/15/2021
			GS220005	11/18/2021
DEPARTMENT OF HEALTH AND HUMAN SERVICES.	Office of Administration for Children and Families.	Special Assistant	DH220022	11/15/2021
	Office of Intergovernmental and External Affairs.	Director, Center for Faith-Based and Neighborhood Partnerships.	DH220021	11/15/2021
		Regional Director, New York, NY, Region II.	DH220016	11/15/2021
		Regional Director, San Francisco, CA, Region IX.	DH220012	11/01/2021
		Regional Director, Seattle, WA, Region X.	DH220011	11/10/2021
	Office of the Assistant Secretary for Administration.	Senior Advisor for Strategic Initiatives.	DH220017	11/15/2021
DEPARTMENT OF HOMELAND SECURITY.	Office of Strategy, Policy, and Plans.	Managing Director for Strategy Office of Cyber, Infrastructure, Risk, and Resilience.	DM220015	11/26/2021
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.	Office of Field Policy and Management.	Regional Administrator (3)	DU220009	11/16/2021
			DU220008	11/22/2021
			DU220011	11/24/2021
	Office of the General Counsel	Senior Counsel	DU220007	11/24/2021
DEPARTMENT OF THE INTERIOR	Secretary's Immediate Office	Advance Representative	DI220001	11/02/2021
		Senior Advisor	DI220007	11/22/2021
DEPARTMENT OF JUSTICE	Office of Justice Programs	Senior Policy Advisor (2)	DJ220013	11/19/2021
			DJ220018	11/30/2021
	Office of Environment and Natural Resources Division.	Chief of Staff and Senior Counsel	DJ220019	11/30/2021
DEPARTMENT OF LABOR	Office of the Secretary	Travelling Special Assistant	DL220010	11/09/2021
	Office of Federal Contract Compliance Programs.	Senior Advisor	DL220004	11/22/2021
	Office of Congressional and Intergovernmental Affairs.	Legislative Officer	DL220009	11/22/2021
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION.	Office of the Administrator	White House Liaison	NN220004	11/10/2021
UNITED STATES INTERNATIONAL DEVELOPMENT FINANCE CORPORATION.	Overseas Private Investment Corporation.	Special Assistant	PQ220001	11/24/2021
DEPARTMENT OF STATE	Office of the Under Secretary for Civilian Security, Democracy, and Human Rights.	Deputy Special Envoy to Monitor and Combat Anti-Semitism.	DS220006	11/16/2021
DEPARTMENT OF TRANSPORTATION.	Office of the Assistant Secretary for Transportation Policy.	Labor Policy Advisor	DT220010	11/29/2021

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF THE TREASURY.	Office of the Assistant Secretary for Terrorist Financing.	Special Assistant	DY220006	11/18/2021

The following Schedule C appointing authorities were revoked during November 2021.

Agency name	Organization name	Position title	Request No.	Vacate date
DEPARTMENT OF EDUCATION	Office of Planning, Evaluation and Policy Development.	Special Assistant	DB210054	11/20/2021
	Office of the Secretary	Confidential Assistant	DB210070	11/05/2021
DEPARTMENT OF JUSTICE	Office of the Associate Attorney General.	Chief of Staff	DJ210132	11/20/2021
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION.	Office of the Administrator	White House Liaison	NN210017	11/06/2021
		Special Assistant for Operations	NN210060	11/20/2021

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2022–15895 Filed 7–25–22; 8:45 am]

BILLING CODE 6325–39–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–601, OMB Control No. 3235–0673]

Proposed Collection; Comment Request; Extension: Rule 15c3–5

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 15c3–5 (17 CFR 240.15c3–5) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 15c3–5 under the Exchange Act requires brokers or dealers with access to trading directly on an exchange or alternative trading system (''ATS''), including those providing sponsored or direct market access to customers or other persons, to implement risk management controls and supervisory procedures reasonably designed to manage the financial, regulatory, and other risks of this business activity.

The rule requires brokers or dealers to establish, document, and maintain certain risk management controls and supervisory procedures as well as regularly review such controls and procedures, and document the review, and remediate issues discovered to assure overall effectiveness of such controls and procedures. Each such broker or dealer is required to preserve a copy of its supervisory procedures and a written description of its risk management controls as part of its books and records in a manner consistent with Rule 17a–4(e)(7) under the Exchange Act. Such regular review is required to be conducted in accordance with written procedures and is required to be documented. The broker or dealer is required to preserve a copy of such written procedures, and documentation of each such review, as part of its books and records in a manner consistent with Rule 17a-4(e)(7) under the Exchange Act, and Rule 17a-4(b) under the Exchange Act, respectively.

In addition, the Chief Executive Officer (or equivalent officer) is required to certify annually that the broker or dealer's risk management controls and supervisory procedures comply with the rule, and that the broker-dealer conducted such review. Such certifications are required to be preserved by the broker or dealer as part of its books and records in a manner consistent with Rule 17a-4(b) under the Exchange Act. Compliance with Rule 15c3–5 is mandatory.

Respondents consist of broker-dealers with access to trading directly on an exchange or ATS. The Commission estimates that there are currently 520 respondents. To comply with Rule 15c3–5, these respondents will spend a total of approximately 83,200 hours per year (160 hours per broker-dealer × 520 broker-dealers = 83,200 hours). At an average internal cost per burden hour of approximately $401.89, the resultant total related internal cost of compliance for these respondents is $33,437,040 per year (83,200 burden hours multiplied by approximately $401.89/hour). In addition, for hardware and software expenses, the Commission estimates that the average annual external cost would be approximately $20,500 per broker-dealer, or $10,660,000 in the aggregate ($20,500 per broker-dealer × 520 brokers and dealers = $10,6660,000).

Written comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing by September 26, 2022.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington,

DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 20, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15914 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–661, OMB Control No. 3235–0721]

Submission for OMB Review; Comment Request: Extension: Form 1–SA

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form 1–SA (17 CFR 239.92) is used to file semiannual reports by Tier 2 issuers under Regulation A, an exemption from registration under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*). Tier 2 issuers under Regulation A conducting offerings of up to $50 million within a 12-month period are required to file Form 1–SA. Form 1–SA provides semiannual, interim financial statements and information about the issuer's liquidity, capital resources and operations after the issuer's second fiscal quarter. The purpose of the Form 1–SA is to better inform the public about companies that have conducted Tier 2 offerings under Regulation A. We estimate that approximately 55 issuers file Form 1–SA annually. We estimate that Form 1–SA takes approximately 188.0427 hours to prepare. We estimate that 85% of the 188.0427 hours per response (159.8363 hours) is prepared by the company for a total annual burden of 8,791 hours (159.8363 hours per response × 55 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by August 25, 2022 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: July 20, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15912 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95328; File No. SR–CBOE–2022–038]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend Rule 5.32

July 20, 2022.

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 7, 2022, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend Rule 5.32. The text of the proposed rule change is provided below.

(additions are *Italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 5.32. Order and Quote Book Processing, Display, Priority, and Execution

(a)–(d) No change.

(e) *Cancel/Replace. If a User submits a cancel/replace message for a resting order, regardless of whether the cancel/replace message modifies any terms of the resting order, the order loses its priority position and is placed in a priority position based on the time the System receives the cancel/replace message, unless the User only (1) decreases the quantity of an order, (2) modifies the Max Floor (if a Reserve Order), or (3) modifies the stop price (if a Stop or Stop-Limit order), in which case the order retains its priority position.* [Depending on how an order is modified, the order may change priority position as follows:

(1) If the price of an order is changed, the order loses position and is placed in a priority position as if the System received the order at the time the order was changed.

(2) If the quantity of an order is decreased, it retains its priority position.

(3) If the quantity of an order is increased, it loses its priority position and is placed in a priority position as if the System received the order at the time the quantity of the order is increased.]

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 5.32(e) to describe the impact on priority of a ''no-change'' order[3] (*i.e.,* an order submitted to cancel or replace a resting order that does not change any

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In this context, the term ''order'' includes bids and offers submitted in bulk messages. A bulk message means a single electronic message a user submits with an M (Market-Maker) capacity to the Exchange in which the User may enter, modify, or cancel up to an Exchange-specified number of bids and offers. *See* Rule 1.1 (definition of bulk message, which provides that the System handles a bulk message bid or offer in the same manner as it handles an order or quote, unless the Rules specify otherwise).

terms of an order) and of a cancel/replace message that does not change the price or size of a resting order but changes another term of an order. Current Rule 5.32(e) describes whether a resting order's priority position may change if it is modified with a cancel/replace message. Specifically, current Rule 5.32(e) states if the price of an order is changed, the order loses position and is placed in a priority position as if the System received the order at the time the order was changed. If the quantity of an order is decreased, it retains its priority position. If the quantity of an order is increased, it loses its priority position and is placed in a priority position as if the System received the order at the time the quantity of the order is increased.

Rule 5.32(e), however, is currently silent regarding how the System handles a cancel-replace message comprised of a no-change order or an order that changes terms other than price and size. The Exchange recently determined that if the System receives a no-change order, the resting order would lose its priority position; however, if the System receives a ''no-change'' bid or offer in a bulk message, the resting bid or offer would not lose its priority position. The Exchange proposes to harmonize the handling of all no-change orders and quotes so that any ''no-change'' order or bulk message bid or offer will lose priority, as well as add to the Rules how the System handles no-change orders. Additionally, the Exchange proposes to codify current System functionality that causes a resting order to lose its priority position if any cancel/replace message is submitted if any term other than the Max Floor (if a Reserve Order) [4] or the stop price (if a Stop or Stop-Limit order [5]) is modified. Therefore, the proposed rule change amends Rule 5.32(e) to state if a User submits a cancel/replace message for a resting order, regardless of whether the cancel/replace message modifies any terms of the resting order, the order loses its priority position and is placed in a priority position based on the time the System receives the cancel/replace message, unless the User only (1) decreases the quantity of an order (as is currently set forth in the Rules), (2) modifies the Max Floor (if a Reserve Order), or (3) modifies the stop price (if a Stop or Stop-Limit order), in which case the order retains its priority position.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market as well as protect investors by adding transparency to the Rules regarding how the System handles cancel/replace messages that change no order terms or change order terms other than price and size. The Exchange believes consistency in handling of all no-change orders and quotes will simplify order handling and thus further benefit investors. The Exchange believes it is reasonable for a user's resting order to lose priority if that user submits a cancel/replace order, including a no-change order, to replace that resting order (other than the three exceptions). Ultimately, the purpose of a cancel and replace message is to replace a resting order with a new order; therefore, it is appropriate for the System to treat that replacement order as a new order for purposes of priority. Despite the fact that a cancel/replace message that does not modify the price or size of a resting order (and thus has no investment purpose), a user elected to send that new order to the Exchange despite having an identical order resting on the Exchange's book and use System capacity to do so. Therefore, the Exchange believes it promotes just and equitable principles of trade to treat that replacement order as a new order for priority purposes. The Exchange believes the proposed rule change encourages users to submit to the Exchange only bona fide cancel/replace orders that have legitimate investment purposes and discourages use of System capacity to send unnecessary message traffic.

As set forth in the current Rule 5.32(e), a cancel/replace order that decreases the size of a resting order would continue to not result in a loss of priority position is an order. The Exchange believes it is appropriate to continue to not have this type of cancel/replace order cause a loss of priority because it is consistent with a partial execution of that order, which would similarly not cause a loss of priority.[9] Unlike a no-change order, an order to reduce the size of a resting order may have a legitimate investment purpose, such as to reduce execution risk. Additionally, the Exchange believes it will remove impediments to and perfect the mechanism of a free and open market as well as protect investors by adding transparency to codify that a change to the Max Floor (if a Reserve Order) or the stop price (if a Stop or Stop-Limit order) will not cause a resting order to lose priority because it is unnecessary given the handling of those orders and the fact that at that time there is no priority to lose. Such handling is consistent with the definitions and handling of both of

[4] A ''Reserve Order'' is a limit order with both a portion of the quantity displayed (''Display Quantity'') and a reserve portion of the quantity (''Reserve Quantity'') not displayed. Both the Display Quantity and Reserve Quantity of the Reserve Order are available for potential execution against incoming orders. When entering a Reserve Order, a User must instruct the Exchange as to the quantity of the order to be initially displayed by the System (''Max Floor''). If the Display Quantity of a Reserve Order is fully executed, the System will, in accordance with the User's instruction, replenish the Display Quantity from the Reserve Quantity using one of the below replenishment instructions. If the remainder of an order is less than the replenishment amount, the System will display the entire remainder of the order. The System creates a new timestamp for both the Display Quantity and Reserve Quantity of the order each time it is replenished from reserve. A User may attach an instruction for random replenishment (where the System randomly replenishes the Display Quantity for the order with a number of contracts not outside a replenishment range, which equals the Max Floor plus and minus a replenishment value established by the User when entering a Reserve Order with a Random Replenishment instruction) or fixed replenishment (the System will replenish the Display Quantity of an order with the number of contracts equal to the Max Floor).

[5] A ''Stop (Stop-Loss)'' order is an order to buy (sell) that becomes a market order when the consolidated last sale price (excluding prices from complex order trades if outside of the NBBO) or NBB (NBO) for a particular option contract is equal to or above (below) the stop price specified by the User. A ''Stop-Limit'' order is an order to buy (sell) that becomes a limit order when the consolidated last sale price (excluding prices from complex order trades if outside the NBBO) or NBB (NBO) for a particular option contract is equal to or above (below) the stop price specified by the User.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] *See* Rule 5.32(d).

those order types. Specifically, as set forth in the definition of a Reserve Order, the Max Floor amount is relevant for replenishment of the Display Quantity of the order after execution, and once replenished, the System creates a new timestamp for both the Display Quantity and Reserve Quantity of the order each time it is replenished from reserve (*i.e.,* prioritizes it in the book at the time of replenishment). Therefore, there is no need for a loss in priority due to a change in the Max Floor amount because that order will have its priority reset once it is replenished with that new amount. Similarly, as set forth in the definitions of Stop and Stop-Limit orders, those orders become market or limit orders, respectively, once triggered and thus placed on the book as market or limit orders and prioritized based on that time. The stop price is the piece of information that determines when these orders will be triggered. As a result, there is no need for an order to lose priority due to a change in the stop price given that those orders have not yet been prioritized on the Book and will be prioritized once triggered and entered into the Book for potential execution.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the System will handle all cancel/replace orders from all users in the same manner. All cancel/replace orders, except for the three exceptions, will cause the resting order to lose priority. The three types of cancel/replace orders that will not cause a resting order to lose priority and are consistent with current order handling rules. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed rule change only impacts priority of orders resting on the Exchange's book and thus will have no impact on terms of an order that are disseminated to market participants or on trading outside of the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be 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–CBOE–2022–038 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–CBOE–2022–038. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website 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 offices of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2022–038, and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15921 Filed 7–25–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95342; File No. SR–C2–2022–015]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules Regarding Complex Orders

July 20, 2022.

Pursuant to the provisions of 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 14, 2022, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (''Commission'') a 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

Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') proposes to amend its Rules regarding complex orders. The text of the proposed rule change is provided in Exhibit 5.

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is also available on the Exchange's website (*https://markets.cboe.com/us/options/regulation/rule_filings/ctwo/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Rules regarding complex orders. Specifically, the Exchange proposes to make trading available for complex orders in any ratio, as well as makes [sic] a clarifying change to the complex order rules.

Currently, the definition of complex order in Rule 1.1 provides that the term ''complex order'' means any order involving the concurrent purchase and/or sale of two or more different series in the same class (the ''legs'' or ''components'' of the complex order), for the same account, in a ratio equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) and for the purposes of executing a particular investment strategy. As such, only complex orders with a ratio equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) may currently be submitted for trading on the Exchange. The proposed rule change amends the definition of complex order in Rule 1.1 to provide that a ''complex order'' is any order involving the concurrent purchase and/or sale of two or more different series in the same class (the ''legs'' or ''components'' of the complex order), for the same account, in any ratio and for the purposes of executing a particular investment strategy. The Exchange notes that its affiliated options exchange, Cboe Options, recently amended its complex order rules in the same manner as proposed herein to permit complex orders with ratios less than one-to-three and greater than three-to-one to be eligible for electronic processing.[3] The Exchange proposes to accept complex orders with ratios larger than three-to-one or smaller than one-to-three for execution in order to provide execution opportunities for all complex orders, including those with investment strategies that do not fit within the three-to-one ratio requirement (which opportunities are afforded to those complex orders submitted to Cboe Options today).

While the proposed rule change will allow complex orders of any ratio to be traded on the Exchange, the Exchange does not propose to extend the complex order priority in Rule 5.33(f)(2)[4] to complex orders with ratios equal to or greater than one-to-three and less than or equal to three-to-one to complex orders with larger ratios. Instead, the proposed rule change amends Rule 5.33(f)(2) to provide that, if a complex order has a ratio less than one-to-three (.333) or greater than three-to-one (3.00), the component(s) of the complex order for the leg(s) with a Customer order at the BBO must execute at a price that improves the price of that Customer order(s) on the Simple Book (the Exchange notes that this proposed rule change is described below in further detail). The proposed rule change also makes certain nonsubstantive changes to the complex priority rule. The Exchange notes that execution of complex orders with any ratio will continue to not be permitted at net prices: (i) that would cause any component of the complex strategy to be executed at a price of zero; (ii) worse than the Synthetic Best Bid or Offer (''SBBO''); (iii) that would cause any component of the complex strategy to be executed at a price worse than the individual component prices on the Simple Book; or (iv) worse than the price that would be available if the complex order legged into the Simple Book.

Specifically, regarding the nonsubstantive changes to Rule 5.33(f)(2), the proposed rule change combines subparagraph (2) with (5) (and reformats the subparagraphs with lettering, which is consistent with the general format of the Exchange Rules), as the provisions are interlinked. Specifically, Rule 5.33(f)(2)(2) provides that the System does not execute a complex order pursuant to 5.33 at a net price worse than the SBBO. Separately, Rule 5.33(f)(2)(5) provides that the System does not execute a complex order pursuant to Rule 5.33 ahead of orders on the Simple Book without improving the BBO on at least one component of the complex strategy by at least $0.01—in other words, a complex order could only execute against complex interest by improving the SBBO (and thus not worse than the SBBO). Because these two provisions are interrelated, the Exchange believes it is appropriate to combine them into proposed Rule 5.33(f)(2)(D).[5] The proposed rule change amends language in proposed Rule 5.33(f)(2)(D) to provide that the System does not execute a complex order pursuant to Rule 5.33 at a net price worse than the SBBO and adds subparagraph (i) to additionally provide that if a complex order has a ratio equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00), at least one component of the complex order must execute at a price that improves the BBO for that component, which is consistent with the current rule and current functionality for complex orders in ratios that may currently be submitted on the Exchange. The proposed nonsubstantive rule changes to restructure Rule 5.33(f)(2) have no impact on complex order priority with respect to complex orders that may

[3] *See* Securities Exchange Act Release No. 94204 (February 9, 2022), 87 FR 8625 (February 15, 2022) (SR–CBOE–2021–046). The Cboe Options' filing SR–CBOE–2021–046 also amended Cboe Option's complex order rules to allow the minimum increment for bids and offers on complex orders with any ratio to be in $0.01 or greater (legs were already permitted to be executed in pennies on Cboe Options). The Exchange notes that Rule 5.33(f)(1) currently provides that the minimum increment for bids and offers on a complex order is $0.01, and the components of a complex order may be executed in $0.01 increments, regardless of the minimum increments otherwise applicable to the individual components of the complex order. As a result, all complex orders (including those with larger ratios as proposed in this filing) and their legs will be able to execute in pennies, and all bids and offers on all complex orders (including those with larger ratios, as proposed) will be able to be expressed in a minimum increment of $0.01.

[4] The System does not execute a complex order pursuant to this Rule 5.33 at a net price (1) that would cause any component of the complex strategy to be executed at a price of zero; (2) worse than the SBBO; (3) that would cause any component of the complex strategy to be executed at a price worse than the individual component price on the Simple Book; (4) worse than the price that would be available if the complex order Legged into the Simple Book; or (5) ahead of orders on the Simple Book without improving the BBO on at least one component of the complex strategy by at least $0.01. The Exchange notes pursuant to Rule 5.33(d)(5) and (e), complex orders will execute against orders and quotes in the Simple Book (including customer orders) prior to executing against complex orders.

[5] The proposed rule change makes other nonsubstantive changes to the sentence structure as a result of the combination of provisions, as well as other nonsubstantive changes to the formatting and paragraph structure for added clarity and consistency with the structure of corresponding Cboe Options Rule 5.33(f)(2).

currently execute on the Exchange and are consistent with and align the Exchange's complex order priority rule with the structure of Cboe Options Rule 5.33(f)(2)(A), which governs Cboe Options complex order priority.[6]

Regarding the proposed rule change to incorporate complex orders with larger-ratios, as proposed, into the complex order priority provision, the proposed rule change adds subparagraph (ii) to Rule 5.33(f)(2)(D), as proposed. As described above, Rule 5.33(f)(2)(D), as proposed, provides that the System does not execute a complex order pursuant to Rule 5.33 at a net price worse than the SBBO, and, as proposed subparagraph (ii) provides, if the complex order has a ratio less than one-to-three (.333) or greater than three-to-one (3.00), the component(s) of the complex order for the leg(s) with a Customer order at the BBO must execute at a price that improves the price of that Customer order(s) on the Simple Book. As a result, to the extent a complex order with a ratio of four-to-one (for example) is submitted for electronic execution, the complex order may be executed at a net debit or credit price only if each leg of the order betters the corresponding bid (offer) of a customer order(s) in the Simple Book. Therefore, the complex order priority rules will continue to protect Customer interest on the Simple Book. The proposed rule change regarding complex order priority for complex order ratios less than one-to-three (.333) or greater than three-to-one (3.00) is consistent with the corresponding complex priority rule on Cboe Options[7] as it applies to complex order ratios less than one-to-three (.333) or greater than three-to-one (3.00) electronically submitted to Cboe Options, as previously approved by the Commission.[8]

The proposed rule change also updates Rule 5.33(g) to reflect that the System accepts for electronic processing complex orders with more than four legs. Current Rule 5.33(g) states that a complex order may execute against orders and quotes resting in the Simple Book pursuant to Rule 5.33(d)(5)(A)(i) and (e)(1) if it can execute in full or in a permissible ratio and if it has no more than a maximum number of legs (which the Exchange determines on a class-by-class basis and may be two, three or four), subject to certain restrictions, including that non-Customer complex orders with two option legs that are both buy or both sell and that are both calls or both puts may not leg into the Simple Book and all complex orders with three or four option legs that are all buy or all sell may not leg into the Simple Book. The proposed rule change modifies the parenthetical regarding legging restrictions to indicate that the maximum number the Exchange may determine on a class-by-class basis may be up to 16, as the Exchange's System currently accepts complex orders with up to that many legs for electronic processing.[9] The proposed rule change makes no changes to which or how complex orders may leg into the Simple Book but rather updates this provision to reflect current functionality. This proposed rule change is consistent with the corresponding Cboe Options Rule 5.33(g).[10]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and benefit investors, because it will provide market participants with execution opportunities on the Exchange for all their complex trading and hedging strategies, regardless of ratio. Market participants may determine that investment and hedging strategies with ratios greater than three-to-one or less than one-to-three are appropriate for their investment purposes, and the Exchange believes it will benefit market participants if they have the flexibility to submit their investment and hedging strategies on the Exchange to achieve their desired investment results. The proposed rule change will further remove impediments to and perfect the mechanism of a free and open market and a national market system, as it will allow complex orders to be submitted on the Exchange in the same manner as complex orders may already be submitted on its affiliated options exchange, Cboe Options,[14] which currently permits orders of any ratio to be submitted to the exchange, as previously approved by the Commission.[15] Additionally, the proposed rule change will continue to protect customer order interest on the Simple Book, as all complex orders with a ratio greater than three-to-one or less than one-to-three will be executed only if each leg of the order improves the price of a customer order on the Simple Book on each leg. Again, as noted above, the proposed rule change regarding

[6] *See* Cboe Options Rule 5.33(f)(2)(A); *and see* Securities Exchange Act Release No. 95006 (May 31, 2022), 87 FR 34334 (June 6, 2022) (SR–CBOE–2022–024).

[7] *See* Cboe Options Rule 5.33(f)(2)(A)(iv)(b). The Exchange notes priority on the Exchange is slightly different than on Cboe Options, has the Exchange does not have the concept of priority customer and thus will always execute complex orders against interest in the Simple Book if possible prior to executing complex orders against other complex interest.

[8] *See* Securities Exchange Act Release No. 94204 (February 9, 2022), 87 FR 8625 (February 15, 2022) (SR–CBOE–2021–046). SR–CBOE–2021–046 did not make any changes to complex orders with ratios equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) available on Cboe Options and Cboe Options continues to allow trading in such complex orders with smaller ratios today. Likewise, the Exchange notes that this proposal does not make any changes to currently permissible complex order ratios (equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00)) and such complex orders with smaller ratios will continue to be available for trading on the Exchange, consistent with Cboe Options.

[9] *See* Cboe Notice C2021060800, *Cboe Options Introduces 16-Leg Maximum for Non-FLEX Complex Orders* (June 8, 2021), *available at* Cboe Options Introduces 16-Leg Maximum for Non-FLEX Complex Orders; *see also Cboe US Options Complex Book Process* (technical specifications last updated April 20, 2022), Section 2.3.2, *available at* US Options Complex Book Process.

[10] *See* Cboe Options Rule 5.33(g); *and see* Securities Exchange Act Release No. 95006 (May 31, 2022), 87 FR 34334 (June 6, 2022) (SR–CBOE–2022–024).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] The Exchange notes that its affiliated options exchange, Cboe EDGX Exchange, Inc. (''EDGX''), also intends to file a similar rule filing to allow complex orders of any ratio to be submitted on EDGX.

[15] *See supra* note 10. Prior to the Commission's approval of SR–CBOE–2022–046, larger ratio complex orders were already permitted to be submitted to Cboe Options' trading floor for execution in open outcry. The Commission's approval of SR–CBOE–2022–046 allowed larger ratio complex orders to be submitted for electronic trading.

complex order priority for complex order ratios less than one-to-three (.333) or greater than three-to-one (3.00) is consistent with the corresponding complex priority rule on Cboe Options as it applies to larger ratio orders submitted for electronic trading on Cboe Options.[16] The nonsubstantive proposed rule change to restructure the provisions regarding complex order priority in Rule 5.33(f)(2) is intended to simplify the rule text regarding when legs of complex orders must improve prices of orders on the Simple Book, while adding clarity to the rule text through an update in its formatting and aligning such provision with the structure of Cboe Option's corresponding complex priority rule. This proposed rule change has no impact on electronic complex order priority while still increasing investor understanding.

The proposed nonsubstantive rule change to the provision regarding complex order legging in Rule 5.33(g) will protect investors, as it merely updates the provision to reflect that the System accepts for electronic processing complex orders with more than four legs. The proposed rule change makes no changes to which or how complex orders may leg into the Simple Book but rather updates this provision to reflect current functionality and align with Cboe Options corresponding rule.[17]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change to allow for complex orders in any ratio to be submitted to the Exchange will impose any burden on intramarket competition, as the proposed rule change will apply in the same manner to all Trading Permit Holders (''TPHs''). TPHs will have the discretion to submit complex orders with any ratio for trading on the Exchange. The Exchange does not believe the proposed rule change will impose any burden on intermarket competition as it relates to the execution of orders on the Exchange and will continue to protect the leg markets, including customer orders on the Simple Book. The Exchange believes the proposed rule change may promote competition, as market participants will have additional flexibility to execute their trading and hedging strategies in any ratio, and in the same manner that is already permitted on the Exchange's affiliated options exchange, Cboe Options. Also, other options exchanges are welcome to modify their systems to permit higher/lower ratio orders to execute electronically or on their trading floors.

The proposed nonsubstantive rule change to restructure the provisions regarding complex order priority in Rule 5.33(f)(2) and the proposed nonsubstantive rule change to Rule 5.33(g) are not intended for competitive purposes, but rather are intended to, respectively, simplify and add clarity to the complex priority rule text and to clarify a provision, reflecting more accurately current System functionality. The Exchange does not believe that the proposed nonsubstantive rule changes will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the change will apply in the same manner to all investors. The proposed nonsubstantive rule changes have no impact on trading and thus will not change how any investors' complex orders are processed or executed on the Exchange. As noted above, the proposed rule changes make no changes to which or how complex orders may leg into the Simple Book. The Exchange does not believe that the proposed nonsubstantive rule changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the proposed rule changes have no impact on how complex orders trade, as they merely make a structural update and clarifying updates.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (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 Act[18] and subparagraph (f)(6) of Rule 19b–4 thereunder.[19]

A proposed rule change filed under Rule 19b–4(f)(6)[20] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[21] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Exchange notes that complex orders with any ratio currently are eligible for electronic processing on Cboe Options, and that the proposal does not introduce any new or novel functionality.[22] The Exchange states that waiver of the operative delay will benefit investors by providing them with the flexibility to submit bona-fide multi-legged trading or hedging strategies in any ratio to the Exchange. In addition, the Exchange states that waiver of the operative delay with respect to the proposed non-substantive rule changes to clarify and simplify rule text will benefit investors by providing additional transparency regarding the Exchange's rules as soon as possible.

The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission believes that the proposal will benefit investors by providing investors with an additional venue for trading complex orders with any ratio, including complex orders with a ratio less than one-to-three or greater than three-to-one. As discussed above, the Commission approved a Cboe Options proposal allowing complex orders with any ratio to trade electronically and to be quoted, as well as executed, in $0.01 increments.[23] The Commission notes that the priority provisions in proposed Exchange Rule 5.33(f)(2)(D)(ii) for complex orders with a ratio less than one-to-three or greater than three-to-one—which require each component leg of such an order with a Customer order at the BBO to execute at a price that improves the price of the Customer order(s) on the Simple Book—are consistent with the requirements of

[16] *See supra* note 9.

[17] *See supra* note 12.

[18] 15 U.S.C. 78s(b)(3)(A)(iii).

[19] 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.

[20] 17 CFR 240.19b–4(f)(6).

[21] 17 CFR 240.19b–4(f)(6)(iii).

[22] *See supra* note 3.

[23] *See id.*

Cboe Options Rule 5.33(f)(2)(A)(iv)(b).[24] Accordingly, the Exchange's proposal to allow market participants to submit complex orders with any ratio to the Exchange does not raise new or novel regulatory issues. The Commission believes that the proposed non-substantive changes to Exchange Rules 5.33(f)(2) will modify the format of that rule so that it is consistent with the format of Cboe Rule 5.33(f)(2), and that the proposed non-substantive change to Exchange Rule 5.33(g) will update the rule and make it consistent with Cboe Rule 5.33(g). Accordingly, the Commission waives the operative delay and designates the proposed rule change operative upon filing.[25]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2022–015 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–C2–2022–015. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the 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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2022–015, and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15934 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[24] As noted above, unlike Cboe Options, the Exchange does not have the concept of a priority customer. *See supra* note 7. The Exchange notes that pursuant to Exchange Rules 5.33(d)(5) and (e), complex orders execute against orders and quotes in the Simple Book (including customer orders) prior to executing against complex orders. *See supra* note 4.

[25] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95334; File No. SR–NYSE–2022–28]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make a Non-Substantive Change to Rule 7.31(a)(2)(B) Regarding Limit Order Price Protection

July 20, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 8, 2022, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make a non-substantive change to Rule 7.31(a)(2)(B) regarding Limit Order Price Protection. The proposed rule change is available on the Exchange's website 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 make a non-substantive change to Rule 7.31(a)(2)(B) regarding Limit Order Price Protection.

Rule 7.31(a)(2)(B) (''Limit Order Price Protection'') provides that a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of $0.15 or a specified percentage away from the National Best Offer (National Best Bid) (''NBO'' and ''NBB,'' respectively). The rule currently states that the ''specified percentage is equal to the corresponding 'numerical guideline' percentage set forth in paragraph (c)(1) of Rule 7.10 (Clearly Erroneous Executions) for the Core Trading Session.'' Pursuant to Rule 7.10(c)(1), those numerical guidelines are as follows: 10% for securities with a reference price up to and including

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

$25.00, 5% for securities with a reference price greater than $25.00 and up to and including $50.00, and 3% for securities with a reference price greater than $50.00.

The Exchange proposes to amend Rule 7.31(a)(2)(B) to delete the cross-reference to Rule 7.10(c)(1) and instead include the specified percentages from Rule 7.10(c)(1) as a table in the text of Rule 7.31(a)(2)(B) itself, as follows:

Reference price	Specified percentage
Greater than $0.00 up to and including $25.00	10
Greater than $25.00 up to and including $50.00	5
Greater than $50.00	3

The Exchange does not propose any change to the percentages themselves or when they would apply. Accordingly, the proposed change would be non-substantive and would raise no novel issues.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and with Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change to Rule 7.31(a)(2)(B) would remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, protect investors and the public interest because deleting the cross-reference to Rule 7.10(c)(1) and instead including the relevant percentages from Rule 7.10(c)(1) in the text of Rule 7.31(a)(2)(B) itself will enhance the clarity of the rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather would be a non-substantive change to delete the cross-reference to Rule 7.10(c)(1) and instead include the relevant percentages from Rule 7.10(c)(1) in the text of Rule 7.31(a)(2)(B) itself.

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 Act[6] and Rule 19b–4(f)(6)[7] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2022–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2022–28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2022–28 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15926 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A).

[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.

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission Small Business Capital Formation Advisory Committee

will hold a public meeting on Tuesday, August 2, 2022, via videoconference.

PLACE: The meeting will be conducted by remote means (videoconference) and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549. Members of the public may watch the webcast of the meeting on the Commission's website at *www.sec.gov.*

STATUS: The meeting will begin at 10:00 a.m. (ET) and will be open to the public. This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

MATTERS TO BE CONSIDERED: The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging businesses and their investors under the federal securities laws.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

(Authority: 5 U.S.C. 552b)

Dated: July 22, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–16096 Filed 7–22–22; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95335; File No. SR–NYSEAMER–2022–30]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make a Non-Substantive Change to Rule 7.31E(a)(2)(B) Regarding Limit Order Price Protection

July 20, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 8, 2022, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make a non-substantive change to Rule 7.31E(a)(2)(B) regarding Limit Order Price Protection. The proposed rule change is available on the Exchange's website 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 make a non-substantive change to Rule 7.31E(a)(2)(B) regarding Limit Order Price Protection.

Rule 7.31E(a)(2)(B) (''Limit Order Price Protection'') provides that a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of $0.15 or a specified percentage away from the National Best Offer (National Best Bid) (''NBO'' and ''NBB,'' respectively). The rule currently states that the ''specified percentage is equal to the corresponding 'numerical guideline' percentage set forth in paragraph (c)(1) of Rule 7.10E (Clearly Erroneous Executions) for the Core Trading Session.'' Pursuant to Rule 7.10E(c)(1), those numerical guidelines are as follows: 10% for securities with a reference price up to and including $25.00, 5% for securities with a reference price greater than $25.00 and up to and including $50.00, and 3% for securities with a reference price greater than $50.00.

The Exchange proposes to amend Rule 7.31E(a)(2)(B) to delete the cross-reference to Rule 7.10E(c)(1) and instead include the specified percentages from Rule 7.10E(c)(1) as a table in the text of Rule 7.31E(a)(2)(B) itself, as follows:

Reference price	Specified percentage
Greater than $0.00 up to and including $25.00	10
Greater than $25.00 up to and including $50.00	5
Greater than $50.00	3

The Exchange does not propose any change to the percentages themselves or when they would apply. Accordingly, the proposed change would be non-substantive and would raise no novel issues.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and with Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change to Rule 7.31E(a)(2)(B) would remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, protect investors and the public interest because deleting the cross-reference to Rule 7.10E(c)(1) and instead including the relevant percentages from Rule 7.10E(c)(1) in the text of Rule 7.31E(a)(2)(B) itself will enhance the clarity of the rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather would be a non-substantive change to delete the cross-reference to Rule 7.10E(c)(1) and instead include the relevant percentages from Rule 7.10E(c)(1) in the text of Rule 7.31E(a)(2)(B) itself.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

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 Act[6] and Rule 19b–4(f)(6)[7] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2022–30 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–NYSEAMER–2022–30. 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 website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2022–30 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15927 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A).

[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.

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95331; File No. SR–Phlx–2022–31]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Clearly Erroneous Pilot to October 20, 2022

July 20, 2022.

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 19, 2022, Nasdaq PHLX LLC (''Phlx'' 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 extend the current pilot program related to Phlx Equity 4, Rule 3312 (Clearly Erroneous Transactions) to the close of business on October 20, 2022.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* 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 extend the current pilot program related to Equity 4, Rule 3312, Clearly Erroneous Transactions, to the close of business on October 20, 2022. The pilot program is currently due to expire on July 20, 2022.

On September 10, 2010, the Commission approved, on a pilot basis, changes to Equity 4, Rule 3312 that, among other things: (i) provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

objective standards set forth in the rule.[3] Following this, on September 30, 2010, the Exchange adopted changes to conform its Rule 3312 to Nasdaq's and BX's rules 11890.[4] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[5] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) a series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[6]

These changes were originally scheduled to operate for a pilot period to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or ''LULD Plan'').[7] In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[8] In light of that change, the Exchange amended Equity 4, Rule 3312 to untie the pilot program's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[9] Subsequently, the Exchange amended Rule 3312 to extend the pilot's effectiveness to the close of business on July 20, 2022.[10]

The Exchange now proposes to amend Equity 4, Rule 3312 to extend the pilot's effectiveness for a further three months until the close of business on October 20, 2022. If the pilot period is not either extended, replaced or approved as permanent, the prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) shall be in effect, and the provisions of paragraphs (g) through (i) shall be null and void.[11] In such an event, the remaining sections of Rule 3312 would continue to apply to all transactions executed on the Exchange. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to Rule 3312.

The Exchange does not propose any additional changes to Equity 4, Rule 3312. Extending the effectiveness of Rule 3312 for an additional three months will provide the Exchange and other self-regulatory organizations additional time to consider whether further amendments to the clearly erroneous execution rules are appropriate.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[12] in general, and Section 6(b)(5) of the Act,[13] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning review of transactions as clearly erroneous. The Exchange believes that extending the clearly erroneous execution pilot under Equity 4, Rule 3312 for an additional three months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal would ensure the continued, uninterrupted operation of harmonized clearly erroneous execution rules across the U.S. equities markets while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals to extend their respective clearly erroneous execution pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[14] and Rule 19b–4(f)(6) thereunder.[15] 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

[3] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–NASDAQ–2010–076).

[4] *See* Securities Exchange Act Release No. 63023 (September 30, 2010), 75 FR 61802 (October 6, 2010) (SR-Phlx-2010–125).

[5] *See* Securities Exchange Act Release No. 68820 (February 1, 2013), 78 FR 9436 (February 8, 2013) (SR-Phlx-2013–12).

[6] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR-Phlx-2014–27).

[7] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[8] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (approving Eighteenth Amendment to LULD Plan).

[9] *See* Securities Exchange Act Release No. 85632 (April 11, 2019), 84 FR 16057 (April 17, 2019) (SR-Phlx-2019–14).

[10] *See* Securities Exchange Act Release No. 94765 (April 20, 2022), 87 FR 24602 (April 26, 2022) (SR-Phlx-2022–19).

[11] *See* notes 3–6, *supra*. The prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) generally provided greater discretion to the Exchange with respect to breaking erroneous trades.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6).

become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [16] and subparagraph (f)(6) of Rule 19b–4 thereunder.[17]

A proposed rule change filed under Rule 19b–4(f)(6) [18] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[19] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30 day operative delay so that the proposal may become operative immediately upon filing. Waiver of the 30-day operative delay would extend the protections provided by the current pilot program, without any changes, while a permanent proposal for clearly erroneous execution reviews is being considered.[20] For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2022–31 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–Phlx–2022–31. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2022–31 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Deputy Secretary.

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BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 240.19b–4(f)(6).

[19] 17 CFR 240.19b–4(f)(6)(iii).

[20] *See* Securities Exchange Act Release No. 95259 (July 12, 2022), 87 FR 42760 (July 18, 2022) (SR–CboeBZX–2022–037).

[21] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95341; File No. SR–NYSENAT–2022–10]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee Schedule Related to Colocation

July 20, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 6, 2022, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fee Schedule related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN''). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN'').[4]

Background

The LCN and the IP network are the two local area networks in the Mahwah Data Center that are available to Users.[5] General Note 5 of the Fee Schedule explains that when a User purchases a service that includes access to the LCN or IP network, it receives connectivity to any of the ''Included Data Products'' that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. The Included Data Products include, among others, the ''NMS feeds,'' which are the Consolidated Tape System and Consolidated Quote System (''CTA'' and ''CQ,'' respectively) data feeds and the Options Price Reporting Authority (''OPRA'') data feed.[6]

Before May 2020, connectivity to the NMS feeds was available on only the LCN and IP networks. In May 2020, the Commission approved the Exchange's proposal to offer Users access to the new ''NMS network,'' an alternate, dedicated network that connects to the NMS feeds faster than the LCN or IP networks.[7] Pursuant to that filing, the Exchange amended the notes regarding the services available in colocation to provide that if a User purchases a service that includes a 10 Gb or 40 Gb LCN or IP network connection, that service would also include a connection to the NMS network of the same size, at no additional charge.

Currently, the NMS feeds are available to Users on all three of the NMS network, IP network, and LCN, but at varying speeds. The NMS feeds are published first to the NMS network, which then republishes them to the IP network, which then republishes them to the LCN. This means that connectivity to the NMS feeds is fastest over the NMS network and slowest over the LCN. This also means that receiving the NMS feeds from more than one of these networks does not provide redundancy protection to Users; if connectivity to the NMS feeds over the NMS network were to be interrupted, so would connectivity to those feeds over the IP network and LCN, since the three networks publish the NMS feeds to each other in sequence.

Despite the Exchange's introduction of the NMS network in May 2020, some Users have failed to avail themselves of the option to receive the NMS feeds over that faster network at no additional cost. Other Users have opted to receive the NMS feeds over the NMS network, but have not yet formally asked the Exchange to stop also sending them the NMS feeds over the other networks (*i.e.,* IP network or LCN) for which those Users have ports.

At the same time, traffic over the LCN has been increasing. Increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements overall for the market data feeds of the Exchange and the Affiliate SROs that are included in the Included Data Products (the ''NYSE Group Market Data'' feeds) over the LCN. As a result, the LCN connections over which some Users continue to receive the NMS feeds are increasingly burdened as the NYSE Group Market Data Feeds continue to grow in size.

To address these issues, the Exchange proposes to remove the NMS feeds from the Included Data Products available on the LCN. Doing so would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN.

To accomplish this change, the Exchange proposes to amend General Note 5 of the Fee Schedule as follows (proposed addition italicized):

5. When a User purchases a service that includes access to the LCN or IP network it receives connectivity to any of the Included Data Products that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. *Connectivity to the NMS feeds is not available over the LCN, but is available over the IP network and the NMS network described below in General Note 6.* Market data fees for the Included Data Products are charged by the provider of the data feed. A User can change the Included Data Products to which it receives connectivity at any time, subject to authorization from the provider of the data feed. The Exchange is not the exclusive method to connect to the Included Data Products.

Application and Impact of the Proposed Changes

Currently, 34 Users receive the NMS feeds over the LCN, but 23 of those 34 Users have access to the NMS network already enabled, such that they also receive the NMS feeds over the NMS network. To implement this proposal with respect to those 23 Users, the Exchange has notified the Users that their connections to the NMS feeds over LCN will be discontinued but that they will continue to receive the NMS feeds over the NMS network.

The other 11 Users that receive the NMS feeds over the LCN do not currently have NMS network access enabled, but are entitled to such access at no additional charge, since their existing LCN service includes a connection of the same size to the NMS network. The Exchange has notified these 11 Users that their connections to the NMS feeds over LCN will be discontinued, and all 11 of them have submitted orders to begin receiving the NMS feeds over an NMS network connection at no additional charge. The Exchange is currently in the process of installing NMS network connections for those 11 Users.[8]

Users would experience no interruption in their ability to connect to the NMS feeds as a result of the proposed change, and would receive the NMS feeds faster as a result of the proposed change. No User would be required to purchase any additional products or services from the Exchange to transition their NMS feed connectivity to the NMS network, or to an IP network connection they have already purchased.

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE Chicago, Inc. (together, the ''Affiliate SROs'') has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2022–27, SR–NYSEAMER–2022–28, SR–NYSEArca–2022–39, and SR–NYSECHX–2022–15.

[5] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 at n.9 (June 6, 2018) (SR–NYSENAT–2018–07). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[6] *See id.*

[7] *See* Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR–NYSEArca–2019–61, SR–NYSENAT–2019–19). *See also* Securities Exchange Act Release No. 88972 (May 29, 2020), 85 FR 34472 (June 4, 2020) (SR–NYSECHX–2020–18).

[8] Seven of these 11 Users also currently have access to the IP network and could have chosen to receive the NMS feeds over their IP network connections at no additional charge, but instead all 11 have opted to receive the NMS feeds over the faster NMS network.

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally. The purchase of any colocation service is completely voluntary and the Fee Schedule is applied uniformly to all Users.

No fees are affected by this proposal.

Implementation Date

The Exchange is in the process of transitioning all remaining Users that receive the NMS feeds over the LCN to begin receiving the feeds over NMS network connections at no additional charge. The Exchange expects this transition process to be completed before October 2022. Once that transition is complete, the Exchange proposes to implement this rule change by Customer Notice, at which point the option of receiving the NMS feeds over the LCN would be removed from the Fee Schedule.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Users that currently receive the NMS feeds on the LCN would receive the same data at a faster speed via the NMS or IP network, with no interruption of their ability to connect to the NMS feeds. Connectivity to the NMS feeds over the NMS network would be available at no additional charge to affected Users, since their existing LCN service includes a connection of the same size to the NMS network. In addition, connectivity to the NMS feeds over the IP network would be at no additional charge to Users that have already purchased access to the IP network. The Exchange believes that providing connectivity to the same feeds at a faster speed at no additional charge would perfect the mechanisms of a free and open market and a national market system.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would simply give Users that currently receive the NMS feeds on the LCN the opportunity to receive the same data at a faster speed via the NMS network or the IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would not permit unfair discrimination between customers, issuers, brokers, or dealers, because the proposed change would apply equally to all Users that currently receive the NMS feeds over the LCN. Nor does the proposed change advantage Users of the LCN over Users of the IP network, since, as indicated in the Fee Schedule, services that include a 10 Gb or 40 Gb LCN or IP connection also include a connection to the NMS network of the same size, at no additional charge.

The Exchange believes that the proposed change would facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because removing the NMS feeds from the LCN would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN. As noted above, increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements for the NYSE Group Market Data feeds over the LCN.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues, but rather would provide Users that currently receive the NMS feeds on the LCN the same data at a faster speed via the NMS or IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.[14]

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the

Continued

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2022–10 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–NYSENAT–2022–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the 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 website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2022–10 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15933 Filed 7–25–22; 8:45 am]

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Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95340; File No. SR–NYSECHX–2022–15]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee Schedule Related To Colocation

July 20, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 6, 2022, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fee Schedule related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN''). The proposed rule change is available on the Exchange's website 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 its Fee Schedule related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN'').[4]

Background

The LCN and the IP network are the two local area networks in the Mahwah Data Center that are available to Users.[5] General Note 5 of the Fee Schedule explains that when a User purchases a service that includes access to the LCN or IP network, it receives connectivity to any of the ''Included Data Products'' that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. The Included Data Products include, among others, the ''NMS feeds,'' which are the Consolidated Tape

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs'') has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2022–27, SR–NYSEAMER–2022–28, SR–NYSEArca–2022–39, and SR–NYSENAT–2022–10.

[5] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 87408 (October 28, 2019), 84 FR 58778 at n.6 (November 1, 2019) (SR–NYSECHX–2019–12). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

System and Consolidated Quote System (''CTA'' and ''CQ,'' respectively) data feeds and the Options Price Reporting Authority (''OPRA'') data feed.[6]

Before May 2020, connectivity to the NMS feeds was available on only the LCN and IP networks. In May 2020, the Commission approved the Exchange's proposal to offer Users access to the new ''NMS network,'' an alternate, dedicated network that connects to the NMS feeds faster than the LCN or IP networks.[7] Pursuant to that filing, the Exchange amended the notes regarding the services available in colocation to provide that if a User purchases a service that includes a 10 Gb or 40 Gb LCN or IP network connection, that service would also include a connection to the NMS network of the same size, at no additional charge.

Currently, the NMS feeds are available to Users on all three of the NMS network, IP network, and LCN, but at varying speeds. The NMS feeds are published first to the NMS network, which then republishes them to the IP network, which then republishes them to the LCN. This means that connectivity to the NMS feeds is fastest over the NMS network and slowest over the LCN. This also means that receiving the NMS feeds from more than one of these networks does not provide redundancy protection to Users; if connectivity to the NMS feeds over the NMS network were to be interrupted, so would connectivity to those feeds over the IP network and LCN, since the three networks publish the NMS feeds to each other in sequence.

Despite the Exchange's introduction of the NMS network in May 2020, some Users have failed to avail themselves of the option to receive the NMS feeds over that faster network at no additional cost. Other Users have opted to receive the NMS feeds over the NMS network, but have not yet formally asked the Exchange to stop also sending them the NMS feeds over the other networks (*i.e.,* IP network or LCN) for which those Users have ports.

At the same time, traffic over the LCN has been increasing. Increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements overall for the market data feeds of the Exchange and the Affiliate SROs that are included in the Included Data Products (the ''NYSE Group Market Data'' feeds) over the LCN. As a result, the LCN connections over which some Users continue to receive the NMS feeds are increasingly burdened as the NYSE Group Market Data Feeds continue to grow in size.

To address these issues, the Exchange proposes to remove the NMS feeds from the Included Data Products available on the LCN. Doing so would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN.

To accomplish this change, the Exchange proposes to amend General Note 5 of the Fee Schedule as follows (proposed addition italicized):

5. When a User purchases a service that includes access to the LCN or IP network it receives connectivity to any of the Included Data Products that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. *Connectivity to the NMS feeds is not available over the LCN, but is available over the IP network and the NMS network described below in General Note 6.* Market data fees for the Included Data Products are charged by the provider of the data feed. A User can change the Included Data Products to which it receives connectivity at any time, subject to authorization from the provider of the data feed. The Exchange is not the exclusive method to connect to the Included Data Products.

Application and Impact of the Proposed Changes

Currently, 34 Users receive the NMS feeds over the LCN, but 23 of those 34 Users have access to the NMS network already enabled, such that they also receive the NMS feeds over the NMS network. To implement this proposal with respect to those 23 Users, the Exchange has notified the Users that their connections to the NMS feeds over LCN will be discontinued but that they will continue to receive the NMS feeds over the NMS network.

The other 11 Users that receive the NMS feeds over the LCN do not currently have NMS network access enabled, but are entitled to such access at no additional charge, since their existing LCN service includes a connection of the same size to the NMS network. The Exchange has notified these 11 Users that their connections to the NMS feeds over LCN will be discontinued, and all 11 of them have submitted orders to begin receiving the NMS feeds over an NMS network connection at no additional charge. The Exchange is currently in the process of installing NMS network connections for those 11 Users.[8]

Users would experience no interruption in their ability to connect to the NMS feeds as a result of the proposed change, and would receive the NMS feeds faster as a result of the proposed change. No User would be required to purchase any additional products or services from the Exchange to transition their NMS feed connectivity to the NMS network, or to an IP network connection they have already purchased.

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally. The purchase of any colocation service is completely voluntary and the Fee Schedule is applied uniformly to all Users.

No fees are affected by this proposal.

Implementation Date

The Exchange is in the process of transitioning all remaining Users that receive the NMS feeds over the LCN to begin receiving the feeds over NMS network connections at no additional charge. The Exchange expects this transition process to be completed before October 2022. Once that transition is complete, the Exchange proposes to implement this rule change by Customer Notice, at which point the option of receiving the NMS feeds over the LCN would be removed from the Fee Schedule.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, because it is

[6] *See id.*

[7] *See* Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR-NYSEArca–2019–61, SR–NYSENAT–2019–19). *See also* Securities Exchange Act Release No. 88972 (May 29, 2020), 85 FR 34472 (June 4, 2020) (SR–NYSECHX–2020–18).

[8] Seven of these 11 Users also currently have access to the IP network and could have chosen to receive the NMS feeds over their IP network connections at no additional charge, but instead all 11 have opted to receive the NMS feeds over the faster NMS network.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Users that currently receive the NMS feeds on the LCN would receive the same data at a faster speed via the NMS or IP network, with no interruption of their ability to connect to the NMS feeds. Connectivity to the NMS feeds over the NMS network would be available at no additional charge to affected Users, since their existing LCN service includes a connection of the same size to the NMS network. In addition, connectivity to the NMS feeds over the IP network would be at no additional charge to Users that have already purchased access to the IP network. The Exchange believes that providing connectivity to the same feeds at a faster speed at no additional charge would perfect the mechanisms of a free and open market and a national market system.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would simply give Users that currently receive the NMS feeds on the LCN the opportunity to receive the same data at a faster speed via the NMS network or the IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would not permit unfair discrimination between customers, issuers, brokers, or dealers, because the proposed change would apply equally to all Users that currently receive the NMS feeds over the LCN. Nor does the proposed change advantage Users of the LCN over Users of the IP network, since, as indicated in the Fee Schedule, services that include a 10 Gb or 40 Gb LCN or IP connection also include a connection to the NMS network of the same size, at no additional charge.

The Exchange believes that the proposed change would facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because removing the NMS feeds from the LCN would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN. As noted above, increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements for the NYSE Group Market Data feeds over the LCN.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues, but rather would provide Users that currently receive the NMS feeds on the LCN the same data at a faster speed via the NMS or IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

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.

[11] 15 U.S.C. 78f(b)(8).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSECHX–2022–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 15 U.S.C. 78s(b)(2)(B).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSECHX–2022–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the 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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSECHX–2022–15 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15932 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–338, OMB Control No. 3235–0376]

Submission for OMB Review; Comment Request: Extension: Schedule 14D–1F

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Schedule 14D–1F (17 CFR 240.14d–102) is a form that may be used by any person (the ''bidder'') making a cash tender or exchange offer for securities of any issuer (the ''target'') incorporated or organized under the laws of Canada or any Canadian province or territory that is a foreign private issuer, where less than 40% of the outstanding class of the target's securities that is the subject of the offer is held by U.S. holders. Schedule 14D–1F is designed to facilitate cross-border transactions in the securities of Canadian issuers. The information required to be filed with the Commission provides security holders with material information regarding the bidder as well as the transaction so that they may make informed investment decisions. The information provided is mandatory and all information is made available to the public upon request. Schedule 14D–1F takes approximately 2 hours per response to prepare and is filed by approximately 2 respondents annually for a total reporting burden of 4 hours (2 hours per response × 2 responses).

An agency may conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by August 25, 2022 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: July 20, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15913 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95329; File No. SR–NASDAQ–2022–043]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Current Pilot Program Related to Nasdaq Equity 11, Rule 11890 (Clearly Erroneous Transactions) to the Close of Business on October 20, 2022

July 20, 2022.

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 19, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' 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 extend the current pilot program related to Nasdaq Equity 11, Rule 11890 (Clearly Erroneous Transactions) to the close of business on October 20, 2022.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* 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.

[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 purpose of the proposed rule change is to extend the current pilot program related to Equity 11, Rule 11890, Clearly Erroneous Transactions, to the close of business on October 20, 2022. The pilot program is currently due to expire on July 20, 2022.

On September 10, 2010, the Commission approved, on a pilot basis, changes to Equity 11, Rule 11890 that, among other things: (i) provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[3] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[4] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) a series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[5]

These changes were originally scheduled to operate for a pilot period to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or ''LULD Plan'').[6] In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[7] In light of that change, the Exchange amended Equity 11, Rule 11890 to untie the pilot program's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[8] Subsequently, the Exchange amended Rule 11890 to extend the pilot's effectiveness to the close of business on July 20, 2022.[9]

The Exchange now proposes to amend Equity 11, Rule 11890 to extend the pilot's effectiveness for a further three months until the close of business on October 20, 2022. If the pilot period is not either extended, replaced or approved as permanent, the prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) shall be in effect, and the provisions of paragraphs (g) through (i) shall be null and void.[10] In such an event, the remaining sections of Rule 11890 would continue to apply to all transactions executed on the Exchange. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to Rule 11890.

The Exchange does not propose any additional changes to Equity 11, Rule 11890. Extending the effectiveness of Rule 11890 for an additional three months will provide the Exchange and other self-regulatory organizations additional time to consider whether further amendments to the clearly erroneous execution rules are appropriate.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[11] in general, and Section 6(b)(5) of the Act,[12] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning review of transactions as clearly erroneous. The Exchange believes that extending the clearly erroneous execution pilot under Equity 11, Rule 11890 for an additional three months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal would ensure the continued, uninterrupted operation of harmonized clearly erroneous execution rules across the U.S. equities markets while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals to extend their respective clearly erroneous execution pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–NASDAQ–2010–076).

[4] *See* Securities Exchange Act Release No. 68819 (February 1, 2013), 78 FR 9438 (February 8, 2013) (SR–NASDAQ–2013–022).

[5] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–NASDAQ–2014–044).

[6] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[7] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (approving Eighteenth Amendment to LULD Plan).

[8] *See* Securities Exchange Act Release No. 85603 (April 11, 2019), 84 FR 16064 (April 17, 2019) (SR–NASDAQ–2019–028).

[9] *See* Securities Exchange Act Release No. 94763 (April 20, 2022), 87 FR 24597 (April 26, 2022) (SR–NASDAQ–2022–033).

[10] *See* notes 3–5, *supra*. The prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) generally provided greater discretion to the Exchange with respect to breaking erroneous trades.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [13] and Rule 19b–4(f)(6) thereunder.[14] 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 Act [15] and subparagraph (f)(6) of Rule 19b–4 thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6) [17] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[18] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30 day operative delay so that the proposal may become operative immediately upon filing. Waiver of the 30-day operative delay would extend the protections provided by the current pilot program, without any changes, while a permanent proposal for clearly erroneous execution reviews is being considered.[19] For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[20]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2022–043 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–NASDAQ–2022–043. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–043 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15922 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] *See* Securities Exchange Act Release No. 95259 (July 12, 2022), 87 FR 42760 (July 18, 2022) (SR-CboeBZX–2022–037).

[20] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95326; File No. SR–OCC–2022–802]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Advance Notice Related to a Master Repurchase Agreement as Part of The Options Clearing Corporation's Overall Liquidity Plan

July 20, 2022.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled Payment, Clearing and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) [2] under the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[3] notice is hereby given that on July 7, 2022, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') an advance notice as described in Items I, II and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This advance notice is submitted in connection a proposed change to its operations in the form of executing a committed master repurchase agreement with a bank counterparty as part of OCC's overall liquidity plan. The proposed changes do not require any changes to the text of OCC's By-Laws or Rules. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[4]

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 15 U.S.C. 78a *et seq.*

[4] OCC's By-Laws and Rules can be found on OCC's public website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A) and (B) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the advance notice and none have been received. OCC will notify the Commission of any written comments received by OCC.

(B) Advance Notices Filed Pursuant to Section 806(e) of the Payment, Clearing, and Settlement Supervision Act

Description of the Proposed Change

As the sole clearing agency for standardized U.S. securities options listed on national securities exchanges registered with the Commission (''listed options''), OCC is obligated to make certain payments. In the event of a Clearing Member default, OCC would be obligated to make payments, on time, related to that member's clear transactions. To meet such payment obligations, OCC maintains access to cash from a variety of sources, including, a requirement for members to pledge cash collateral to OCC and various agreements with banks and other counterparties (''liquidity facilities'') to provide OCC with cash in exchange for collateral, such as U.S. Government securities. OCC routinely considers potential market stress scenarios that could affect such payment obligations. Based on such considerations, OCC now believes that it should seek to expand its liquidity facility to increase OCC's access to cash to manage a member default.

OCC is proposing to expand its liquidity facilities to include a new arrangement with a bank to provide cash to OCC. Specifically, this advance notice concerns a change to OCC's operations to execute a master repurchase agreement with a bank counterparty as part of OCC's overall liquidity plan, which includes OCC's arrangements to access cash in exchange for U.S. Government securities deposited by Clearing Members in respect of their Clearing Fund requirements to meet OCC's settlement obligations. OCC is not, as part of this advance notice, proposing to require its members or other market participants provide additional or different collateral to OCC. Rather, the purpose of the proposal is to provide OCC with another vehicle for accessing cash to meet its payment obligations, including in the event that one of its members fails to meet its payment obligations to OCC.[5]

Background

OCC's current liquidity plan provides it with access to a diverse set of funding sources, including banks (*i.e.,* OCC's syndicated credit facility),[6] the Non-Bank Liquidity Facility program,[7] and Clearing Members' Cash Clearing Fund Requirement.[8] OCC is proposing to add to these sources a master repurchase agreement (''MRA'') with a bank counterparty (the ''Bank Repo Facility program''). This program would mirror the Repo Liquidity Facility that OCC executed with a bank counterparty in 2020 after obtaining a notice of no objection from the Commission (''2020 Bank Repo Facility''),[9] except that in this case, the committed amount will be up to $1 billion (as opposed to $500 million) and the bank counterparty will be one to which OCC has minimal other credit exposure. The counterparty would be one that has already been approved by OCC as a liquidity provider and would be subject to routine monitoring under OCC's Third-Party Risk Management Framework,[10] which meets or exceeds the monitoring process discussed in the advance notice for the 2020 Bank Repo Facility.[11]

Although the MRA would be based on the standard form of master repurchase agreement,[12] OCC would require the MRA, or an annex thereto, to contain certain additional provisions tailored to help ensure certainty of funding and operational effectiveness, as described in more detail below. OCC believes that these provisions are necessary and appropriate to integrate the program into its operations and in order to promote safety and soundness consistent with OCC's systemic responsibilities. OCC provided a summary of the additional terms and conditions (''Summary of Terms'') as presented to the Board in confidential Exhibit 3 to File No. SR–OCC–2022–802.[13] Because the arrangements between OCC and the bank counterparty have not been fully negotiated, OCC has identified the following as key standards that would need to be incorporated into the MRA.

The Proposed Program: Standard Repurchase Agreement Terms

The MRA would be structured like a typical repurchase arrangement in which the buyer (*i.e.,* the bank counterparty) would purchase from OCC, from time to time, U.S. Government securities (''Eligible Securities'').[14] OCC, as the seller, would transfer Eligible Securities to the buyer in exchange for a payment by the buyer to OCC in immediately available funds (''Purchase Price''). The buyer would simultaneously agree to transfer the purchased securities back to OCC at a specified later date (''Repurchase Date'') or on OCC's demand against the transfer of funds by OCC to the buyer in an amount equal to the outstanding Purchase Price plus the accrued and

[5] OCC may also use the Clearing Fund to address liquidity shortfalls arising from the failure of any bank, securities or commodities clearing organization, or investment counterparty to perform any obligation to OCC when due. *See* OCC Rule 1006(f)(1)(C); Exchange Act Release No. 94304 (Feb. 24, 2022), 87 FR 11776 (Mar. 2, 2022) (SR–OCC–2021–014).

[6] *See* Exchange Act Release No. 88971 (May 28, 2020), 85 FR 34257 (June 3, 2020) (SR–OCC–2020–804).

[7] *See* Exchange Act Release No. 89039 (June 10, 2020), 85 FR 36444 (June 16, 2020) (SR–OCC–2020–803); Exchange Act Release No. 76821 (Jan. 4, 2016), 81 FR 3208 (Jan. 20, 2016) (SR–OCC–2015–805); Exchange Act Release No. 73979 (Jan. 2, 2015), 80 FR 1062 (Jan. 8, 2015) (SR–OCC–2014–809).

[8] *See* OCC Rule 1002.

[9] *See* Exchange Act Release No. 88317 (Mar. 4, 2020), 85 FR 13681 (Mar. 9, 2020) (SR–OCC–2020–801).

[10] *See* Exchange Act Release No. 90797 (Dec. 23, 2020), 85 FR 86592 (Dec. 30, 2020) (SR–OCC–2020–014). The Third-Party Risk Management Framework is available on OCC's public website. *See* Documents & Archives, *https://www.theocc.com/Company-Information/Documents-and-Archives.*

[11] *See* Exchange Act Release No. 88120 (Feb. 5, 2020), 85 FR 7812 (Feb. 11, 2020) (SR–OCC–2020–801).

[12] The standard form master repurchase agreement is published by the Securities Industry and Financial Markets Association (''SIFMA'') and is commonly used in the repurchase market by institutional investors.

[13] In addition to the Summary of Terms, the confidential Exhibit 3 to File No. SR–OCC–2022–802 includes a summary of OCC management's recommendation to expand OCC's external liquidity sources as well as a discussion of the analysis underlying that recommendation.

[14] OCC would use U.S. government securities that are included in Clearing Fund contributions by Clearing Members and margin deposits of any Clearing Member that has been suspended by OCC for the repurchase arrangements. OCC Rule 1006(f) and OCC Rule 1104(b) authorize OCC to obtain funds from third parties through securities repurchases using these sources. The officers who may exercise this authority include the Chairman, Chief Executive Officer, and Chief Operating Officer.

unpaid price differential (together, ''Repurchase Price''), which is the interest component of the Repurchase Price.

At all times while a transaction is outstanding, OCC would be required to maintain a specified amount of securities or cash margin with the buyer.[15] The market value of the securities supporting each transaction would be determined daily, typically based on a price obtained from a generally recognized pricing source. If the market value of the purchased securities is determined to have fallen below OCC's required margin, OCC would be required to transfer to the buyer sufficient cash or additional securities reasonably acceptable to the buyer so that OCC's margin requirement is satisfied.[16] If the market value of the purchased securities is determined to have risen to above OCC's required margin, OCC would be permitted to require the return of excess purchased securities from the buyer.

As in a typical master repurchase agreement, an event of default would occur with respect to the buyer if the buyer failed to purchase securities on a Purchase Date, failed to transfer purchased securities on any applicable Repurchase Date, or failed to transfer any interest, dividends or distributions on purchased securities to OCC within a specified period after receiving notice of such failure. An event of default would occur with respect to OCC if OCC failed to transfer purchased securities on a Purchase Date or failed to repurchase purchased securities on an applicable Repurchase Date. The MRA would also provide for standard events of default for either party, including a party's failure to maintain required margin or an insolvency event with respect to the party. Upon the occurrence of an event of default, the non-defaulting party, at its option, would have the right to accelerate the Repurchase Date of all outstanding transactions between the defaulting party and the non-defaulting party, among other rights. For example, if OCC were the defaulting party with respect to a transaction and the buyer chose to terminate the transaction, OCC would be required to immediately transfer the Repurchase Price to the buyer. If the buyer were the defaulting party with respect to a transaction and OCC chose to terminate the transaction, the buyer would be required to deliver all purchased securities to OCC. If OCC or the buyer did not timely perform, the non-defaulting party would be permitted to buy or sell, or deem itself to have bought or sold, securities as needed to be made whole and the defaulting party would be required to pay the costs related to any covering transactions. Additionally, if OCC was required to obtain replacement securities as a result of an event of default, the buyer would be required to pay the excess of the price paid by OCC to obtain replacement securities over the Repurchase Price.

The Proposed Program: Customized Features To Promote Certainty of Funding and Operational Effectiveness

In addition to the typical repurchase arrangements, OCC would require the MRA, or an annex thereto, to contain certain additional provisions tailored to help ensure certainty of funding and operational effectiveness.[17]

Commitment to Fund

The buyer would provide a funding commitment of up to $1 billion, with the commitment extending for one year (plus or minus one day). The buyer would be obligated to enter into transactions under the MRA up to its committed amount so long as no default had occurred and OCC transferred sufficient Eligible Securities. The buyer would be obligated to enter into transactions even if OCC had experienced a material adverse change, such as the failure of a Clearing Member. This commitment to provide funding would be a key departure from ordinary repurchase arrangements and a key requirement for OCC.

Funding Mechanics

Funding mechanics would be targeted so that OCC would receive the Purchase Price in immediately available funds within 60 minutes of its request for funds and delivery of Eligible Securities and, if needed, prior to OCC's regular daily settlement time.[18] These targeted funding mechanics would allow OCC to receive needed liquidity in time to satisfy settlement obligations, even in the event of a default by a Clearing Member or a market disruption. The funding mechanism may be, for example, delivery versus payment/receive versus payment[19] or another method acceptable to OCC that both satisfies the objectives of the Bank Repo Facility and presents limited operational risks.[20]

No Rehypothecation

The buyer would not be permitted to grant any third party an interest in purchased securities. This requirement is important to reduce the risk that a third party could interfere with the buyer's transfer of the purchased securities on the Repurchase Date. Further, the buyer would agree to provide OCC with daily information about the account the buyer uses to hold the purchased securities. This visibility would allow OCC to act quickly in the event the buyer violates any requirements.

Early Termination Rights

OCC would have the ability to terminate any transaction upon written notice to the buyer, but the buyer would only be able to terminate a transaction upon the occurrence of an event of default with respect to OCC, as further described below. A notice of termination by OCC would specify a new Repurchase Date prior to the originally agreed upon Repurchase Date. Upon the early termination of a transaction, the buyer would be required to return all purchased securities to OCC and OCC would be required to pay the Repurchase Price. This optional early termination right is important to OCC because OCC's liquidity needs may change unexpectedly over time and as a result OCC may not want to keep a transaction outstanding as long as originally planned.

Substitution

OCC would have the ability to substitute any Eligible Securities for purchased securities in its discretion by a specified time, so long as the Eligible Securities satisfy any applicable criteria contained in the MRA and the transfer of the Eligible Securities would not create a margin deficit, as described

[15] OCC expects that it would be required to maintain margin equal to 102% of the Repurchase Price, which is a standard rate for arrangements involving Government securities.

[16] OCC expects that it would use Clearing Fund securities and securities posted as margin by defaulting Clearing Members, as more fully discussed in footnote 14.

[17] OCC expects that the MRA will also include other, more routine, provisions such as the method for giving notices and basic due authorization representations by the parties.

[18] This would include OCC's regular daily settlement time and any extended settlement time implemented by OCC in an emergency situation under Rule 505.

[19] Delivery versus payment/receive versus payment is a method of settlement under which payment for securities must be made prior to or simultaneously with delivery of the securities.

[20] Unlike for the Non-Bank Liquidity Facility, OCC would not require the Bank Repo Facility counterparty to maintain cash and investments in a designated account in which OCC has visibility. OCC required a designated account for Non-Bank Liquidity Facility counterparties in order to facilitate prompt funding by counterparties that, unlike the Bank Repo Facility counterparty, are not commercial banks and therefore are not in the business of daily funding.

above.[21] This substitution right is important to OCC because it must be able to manage requests of Clearing Members to return excess or substitute Eligible Securities in accordance with established operational procedures.

Events of Default

Beyond the standard events of default for a failure to purchase or transfer securities on the applicable Purchase Date or Repurchase Date, as described above, OCC would require that the MRA not contain any additional events of default that would restrict OCC's access to funding. Most importantly, OCC would require that it would not be an event of default if OCC suffers a ''material adverse change.'' [22] This provision is important because it provides OCC with certainty of funding, even in difficult market conditions.

The agreement also provides that upon the occurrence of an event of default, in addition to the non-defaulting party's right to accelerate the Repurchase Date of all outstanding transactions or to buy or sell securities as needed to be made whole, the non-defaulting party may elect to take the actions specified in a ''mini close-out'' provision of the MRA rather than declaring an event of default. For example, if the buyer fails to transfer purchased securities on the applicable Repurchase Date, rather than declaring an event of default, OCC may (1) if OCC has already paid the Repurchase Price, require the buyer to repay the Repurchase Price, (2) if there is a margin excess, require the buyer to pay cash or delivered purchased securities in an amount equal to the margin excess, or (3) declare that the applicable transaction, and only that transaction, will be immediately terminated, and apply default remedies under the MRA to only that transaction. Therefore, if the buyer fails to deliver purchased securities on any Repurchase Date, OCC would have remedies that allow it to mitigate risk with respect to a particular transaction, without declaring an event of default with respect to all transactions under the MRA.

The Proposed Program: Annual Renewal

As discussed above, MRA would be for an annual term. OCC anticipates that it will renew the MRA with the same bank counterparty based on the same or substantially similar terms. At each renewal, OCC would evaluate the commitment amount so that OCC's available liquidity resources remain properly calibrated to its activities and settlement obligations. OCC would submit another advance notice with respect to such renewal for the same term only if: (i) OCC determines its liquidity needs merit funding levels above the $1 billion, (ii) OCC should seek to change the terms and conditions of the MRA in a manner that materially affects the nature or level of risk presented by OCC,[23] (iii) OCC should seek to add counterparties or substitute the bank counterparty to the Bank Repo Facility program, or (iv) the bank counterparty has experienced a negative change to its credit profile or a material adverse change since the latest renewal of the MRA. As such, annual renewals for the Bank Liquidity Facility would proceed in a similar manner to renewals of term commitments under the Non-Bank Liquidity Facility—another MRA liquidity source.[24]

OCC does not believe that, absent one or more of the changes described above, renewal of the MRA would constitute a change to OCC's operations that could materially affect the nature or level of risks presented by OCC so as to require an advance notice under Section 806(e)(1) of the Clearing Supervision Act.[25] Accordingly OCC would consider such a renewal to be on substantially the same terms and conditions such that executing such renewal would not be subject to the requirement to file an advance notice filing pursuant to Section 806(e)(1) of the Clearing Supervision Act.[26] If OCC determines to make changes to the Bank Repo Facility in a subsequent filing, it would include in that filing the proposed conditions to the terms of any renewals that could be done without an additional advance notice.

Anticipated Effect on and Management of Risk

Completing timely settlement is a key aspect of OCC's role as a clearing agency performing central counterparty services. OCC believes that the overall impact of the Bank Repo Facility on the risks presented by OCC would be to reduce settlement risk associated with OCC's operations as the clearing agency for all listed options. The Bank Repo Facility would reduce settlement risk by providing an additional source of liquidity that would promote the reduction of risks to OCC, its Clearing Members and the options market in general because it would allow OCC to obtain short-term funds to address liquidity demands arising out of the default or suspension of a Clearing Member, in anticipation of a potential default or suspension of Clearing Members, the insolvency of a bank, another securities or commodities clearing organization, or a counterparty with which OCC has invested Clearing Member funds, or the failure of such a bank, clearing organization or investment counterparty to meet an obligation to OCC when due. The resulting reduction in OCC settlement risk would lead to a corresponding reduction in systemic risk and would have a positive impact on the safety and soundness of the clearing system by enabling OCC to have continuous access to funds to settle its obligations to its Clearing Members. In order to sufficiently perform this key role in promoting market stability, it is critical that OCC continuously has access to funds to settle its obligations.

Providing for another committed source of liquidity resources would also help OCC manage the allocation between its sources of liquidity by giving OCC more flexibility to adjust the

[21] In addition to its substitution rights, OCC could cause the return of purchased securities by exercising its optional early termination rights under the Master Repurchase Agreement. If OCC were to terminate the transaction, the buyer would be required to return purchased securities to OCC against payment of the corresponding Repurchase Price.

[22] When included in a contract, a ''material adverse change'' is typically defined as a change that would have a materially adverse effect on the business or financial condition of a company.

[23] For the purposes of clarity, OCC would not consider changes to pricing or changes in representations, covenants, and terms of events of default, to be changes to a term or condition that would require the filing of a subsequent advance notice provided that pricing is at the then prevailing market rate and changes to such other provisions are immaterial to OCC as the seller and do not impair materially OCC's ability to draw against the facility.

[24] *See* Exchange Act Release No. 76821, 81 FR at 3209 (describing OCC's proposal to submit an advance notice in connection with a renewal of commitments under the Non-Bank Liquidity Facility if: (i) OCC determined that its liquidity needs merited commitments above or below certain levels; (ii) OCC should seek to change the terms and conditions of the Non-Bank Liquidity Facility; and (iii) the commitment counterparty experienced a negative change to its credit profile or a material adverse change since entering the commitment or the latest renewal of the commitment). OCC subsequently submitted an advance notice pursuant to that commitment to support its ability to onboard multiple liquidity providers below the identified thresholds and with different term lengths to replace expiring commitments, *see* Exchange Act Release No. 89039, 85 FR at 36445–46, and has, concurrent with the filing of SR–OCC–2022–802, submitted another advance notice to eliminate the current cap to that program in favor of a floor for external liquidity across all sources. The Bank Repo Facility would retain a cap and a limit on adding new counterparties because OCC is proposing this facility as a discrete MRA with a single counterparty. To the extent OCC determines to add additional commitments or counterparties to the Bank Repo Facility in the future, OCC would first file an advance notice.

[25] 12 U.S.C. 5465(e)(1).

[26] *Id.*

mix of liquidity resources based on market conditions, availability and shifting liquidity needs. If circumstances arise that affect OCC's current liquidity resources from another of its facilities, an additional source of liquidity resources would allow OCC to reallocate liquidity resources as necessary to avoid a shortfall in its overall liquidity resources.[27]

The Bank Repo Facility, like any liquidity source, would involve certain risks, but OCC would structure the program to mitigate those risks. Most of these risks are standard in any master repurchase agreement. For example, the buyer could fail to deliver, or delay in delivering, purchased securities to OCC by the applicable Repurchase Date. OCC will address this risk by seeking a security interest from the buyer in that portion of the purchased securities representing the excess of the market value over the Repurchase Price, or by obtaining other comfort from the buyer that the purchased securities will be timely returned. Further, the purchased securities generally will not be ''on-the-run'' securities, *i.e.,* the most recently issued Treasury securities. The demand in the marketplace for Treasury securities, for uses other than collateral, is much greater for on-the-run Treasury securities, and therefore, OCC believes the buyer will have little incentive to retain the securities transferred by OCC.

The mechanics under the Bank Repo Facility would be structured so that OCC could avoid losses by paying the Repurchase Price. For example, OCC will have optional early termination rights, under which OCC would be able to accelerate the Repurchase Date of any transaction by providing written notice to the buyer and paying the Repurchase Price. Through this mechanism, OCC can maintain the benefit of the Bank Repo Facility, while mitigating any risk associated with a particular transaction.

The Bank Repo Facility would be structured to avoid potential third-party risks, which are typical of repurchase arrangements. The prohibition on buyer rehypothecation and use of purchased securities would reduce the risk to OCC of a buyer default.

As with any repurchase arrangement, OCC is subject to the risk that it may have to terminate existing transactions and accelerate the applicable Repurchase Date with respect to the buyer due to changes in the financial health or performance of the buyer. Terminating transactions could negatively affect OCC's liquidity position. However, any negative effect is reduced by the fact that OCC maintains a number of different financing arrangements, and thus will have access to liquidity sources in the event the Bank Repo Facility is no longer a viable source.

Under the MRA, OCC would be obligated to transfer additional cash or securities as margin in the event the market value of any purchased securities decreases. OCC seeks to ensure it can meet any such obligation by monitoring the value of the purchased securities and maintaining adequate cash resources to make any required payments. Such payments are expected to be small in comparison to the total amount of cash received for each transfer of purchased securities.

Consistency With the Payment, Clearing and Settlement Supervision Act

The stated purpose of the Clearing Supervision Act is to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[28] Section 805(a)(2) of the Clearing Supervision Act[29] also authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities, like OCC, for which the Commission is the supervisory agency. Section 805(b) of the Clearing Supervision Act[30] states that the objectives and principles for risk management standards prescribed under Section 805(a) shall be to:

- promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.

The Commission has adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act and the Exchange Act in furtherance of these objectives and principles.[31] Rule 17Ad–22 requires registered clearing agencies, like OCC, to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[32] Therefore, the Commission has stated[33] that it believes it is appropriate to review changes proposed in advance notices against Rule 17Ad–22 and the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act.[34]

OCC believes that the proposed changes are consistent with Section 805(b)(1) of the Clearing Supervision Act[35] because the proposed Bank Repo Facility would provide OCC with an additional source of committed liquidity to meet its settlement obligations while at the same time being structured to mitigate certain operational risks, as described above, that arise in connection with this committed liquidity source. In this way, the proposed changes are designed to promote robust risk management; promote safety and soundness; reduce systemic risks; and support the stability of the broader financial system.

OCC believes that the Bank Repo Facility is also consistent with the requirements of Rule 17Ad–22(e)(7) under the Act.[36] Rule 17Ad–22(e)(7) requires OCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively measure, monitor, and manage liquidity risk that arises in or is borne by OCC, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity, as specified in the rule.[37] In particular, Rule 17Ad–22(e)(7)(i) under the Act[38] directs that OCC meet this obligation by, among other things, ''[m]aintaining sufficient liquid resources at the minimum in all relevant currencies to effect same-day . . . settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios that includes, but is not limited to, the default of the participant family that would generate the largest aggregate payment obligation for [OCC] in extreme but plausible market conditions.''

As described above, the Bank Repo Facility would provide OCC with a readily available liquidity resource that

[27] For example, OCC has authority under OCC Rule 1002(a)(i) to temporarily increase the cash funding requirement in its Clearing Fund for the protection of OCC, Clearing Members or the general public.

[28] 12 U.S.C. 5461(b).

[29] 12 U.S.C. 5464(a)(2).

[30] 12 U.S.C. 5464(b).

[31] 17 CFR 240.17Ad–22. *See* Securities Exchange Act Release Nos. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11) (''Clearing Agency Standards''); 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (''Standards for Covered Clearing Agencies'').

[32] 17 CFR 240.17Ad–22.

[33] *See, e.g.,* Securities Exchange Act Release No. 86182 (June 24, 2019), 84 FR 31128, 31129 (June 28, 2019) (SR–OCC–2019–803).

[34] 12 U.S.C. 5464(b).

[35] 12 U.S.C. 5464(b)(1).

[36] 17 CFR 240.17Ad–22(e)(7).

[37] *Id.*

[38] 17 CFR 240.17Ad–22(e)(7)(i).

would enable it to, among other things, continue to meet its obligations in a timely fashion and as an alternative to selling Clearing Member collateral under what may be stressed and volatile market conditions. For these reasons, OCC believes that the proposal is consistent with Rule 17Ad–22(e)(7)(i).[39]

Rule 17Ad–22(e)(7)(ii) under the Act requires OCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to hold qualifying liquid resources sufficient to satisfy payment obligations owed to Clearing Members.[40] Rule 17Ad–22(a)(14) of the Act defines ''qualifying liquid resources'' to include, among other things, lines of credit without material adverse change provisions, that are readily available and convertible into cash.[41] The MRA under the Bank Repo Facility would not be subject to any material adverse change provision and would be designed to permit OCC to, among other things, help ensure that OCC has sufficient, readily-available qualifying liquid resources to meet the cash settlement obligations of its largest Clearing Member Group. Therefore, OCC believes that the proposal is consistent with Rule 17Ad–22(e)(7)(ii).[42]

For the foregoing reasons, OCC believes that the proposed changes are consistent with Section 805(b)(1) of the Clearing Supervision Act[43] and Rule 17Ad–22(e)(7)[44] under the Act.

III. Date of Effectiveness of the Advance Notice and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date the proposed change was filed with the Commission or (ii) the date any additional information requested by the Commission is received. OCC shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

OCC shall post notice on its website of proposed changes that are implemented. The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the advance notice 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–OCC–2022–802 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2022–802. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the advance notice that are filed with the Commission, and all written communications relating to the advance notice 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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–OCC–2022–802 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15919 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[39] *Id.*

[40] 17 CFR 240.17Ad–22(e)(7)(ii).

[41] 17 CFR 240.17Ad–22(a)(14).

[42] 17 CFR 240.17Ad–22(e)(7)(ii).

[43] 12 U.S.C. 5464(b)(1).

[44] 17 CFR 240.17Ad–22(e)(7).

[45] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–049, OMB Control No. 3235–0070]

Submission for OMB Review; Comment Request: Extension: Form 10–Q

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection[s] of information discussed below.

Form 10–Q (17 CFR 249.308a) is filed by issuers of securities to satisfy their quarterly reporting obligations pursuant to Section 13 or 15(d) of the Exchange Act (''Exchange Act'') (15 U.S.C. 78m or 78o(d)). The information provided by Form 10–Q is intended to ensure the adequacy of information available to investors about an issuer. Form 10–Q takes approximately 182.08663 hours per response to prepare and is filed by approximately 22,925 respondents. We estimated that 75% of the approximately 182.08663 hours per response (136.56497 hours) is prepared by the company for an annual reporting burden of 3,130,752 hours (136.56497 hours per response × 22,925 responses).

An agency may conduct or sponsor, and a person is not required to respond

to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by August 25, 2022 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: July 20, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15911 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95338; File No. SR–NYSEAMER–2022–28]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE American Equities Price List and Fee Schedule and the NYSE American Options Fee Schedule Related to Colocation

July 20, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 6, 2022, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE American Equities Price List and Fee Schedule and the NYSE American Options Fee Schedule (together, the ''Price List and Fee Schedule'') related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN''). The proposed rule change is available on the Exchange's website 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 its Price List and Fee Schedule related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN'').[4]

Background

The LCN and the IP network are the two local area networks in the Mahwah Data Center that are available to Users.[5] General Note 5 of the Price List and Fee Schedule explains that when a User purchases a service that includes access to the LCN or IP network, it receives connectivity to any of the ''Included Data Products'' that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. The Included Data Products include, among others, the ''NMS feeds,'' which are the Consolidated Tape System and Consolidated Quote System (''CTA'' and ''CQ,'' respectively) data feeds and the Options Price Reporting Authority (''OPRA'') data feed.[6]

Before May 2020, connectivity to the NMS feeds was available on only the LCN and IP networks. In May 2020, the Commission approved the Exchange's proposal to offer Users access to the new ''NMS network,'' an alternate, dedicated network that connects to the NMS feeds faster than the LCN or IP networks.[7] Pursuant to that filing, the Exchange amended the notes regarding the services available in colocation to provide that if a User purchases a service that includes a 10 Gb or 40 Gb LCN or IP network connection, that service would also include a connection to the NMS network of the same size, at no additional charge.

Currently, the NMS feeds are available to Users on all three of the NMS network, IP network, and LCN, but at varying speeds. The NMS feeds are published first to the NMS network, which then republishes them to the IP network, which then republishes them to the LCN. This means that connectivity to the NMS feeds is fastest over the NMS network and slowest over the LCN. This also means that receiving the NMS feeds from more than one of these networks does not provide redundancy protection to Users; if connectivity to the NMS feeds over the NMS network were to be interrupted, so would connectivity to those feeds over the IP network and LCN, since the three networks publish the NMS feeds to each other in sequence.

Despite the Exchange's introduction of the NMS network in May 2020, some Users have failed to avail themselves of the option to receive the NMS feeds over that faster network at no additional cost. Other Users have opted to receive the NMS feeds over the NMS network, but have not yet formally asked the Exchange to stop also sending them the NMS feeds over the other networks (*i.e.,*

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates New York Stock Exchange, LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs'') has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2022–27, SR–NYSEArca–2022–39, SR–NYSECHX–2022–15, and SR–NYSENAT–2022–10.

[5] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR–NYSEMKT–2015–67). As specified in the Price List and Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[6] *See* Securities Exchange Act Release No. 79728 (January 4, 2017), 82 FR 3035 (January 10, 2017) (SR–NYSEMKT–2016–126).

[7] *See* Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR–NYSEArca–2019–61, SR–NYSENAT–2019–19). *See also* Securities Exchange Act Release No. 88972 (May 29, 2020), 85 FR 34472 (June 4, 2020) (SR–NYSECHX–2020–18).

IP network or LCN) for which those Users have ports.

At the same time, traffic over the LCN has been increasing. Increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements overall for the market data feeds of the Exchange and the Affiliate SROs that are included in the Included Data Products (the ''NYSE Group Market Data'' feeds) over the LCN. As a result, the LCN connections over which some Users continue to receive the NMS feeds are increasingly burdened as the NYSE Group Market Data Feeds continue to grow in size.

To address these issues, the Exchange proposes to remove the NMS feeds from the Included Data Products available on the LCN. Doing so would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN.

To accomplish this change, the Exchange proposes to amend General Note 5 of the Price List and Fee Schedule as follows (proposed addition italicized):

5. When a User purchases a service that includes access to the LCN or IP network it receives connectivity to any of the Included Data Products that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. *Connectivity to the NMS feeds is not available over the LCN, but is available over the IP network and the NMS network described below in General Note 6.* Market data fees for the Included Data Products are charged by the provider of the data feed. A User can change the Included Data Products to which it receives connectivity at any time, subject to authorization from the provider of the data feed. The Exchange is not the exclusive method to connect to the Included Data Products.

Application and Impact of the Proposed Changes

Currently, 34 Users receive the NMS feeds over the LCN, but 23 of those 34 Users have access to the NMS network already enabled, such that they also receive the NMS feeds over the NMS network. To implement this proposal with respect to those 23 Users, the Exchange has notified the Users that their connections to the NMS feeds over LCN will be discontinued but that they will continue to receive the NMS feeds over the NMS network.

The other 11 Users that receive the NMS feeds over the LCN do not currently have NMS network access enabled, but are entitled to such access at no additional charge, since their existing LCN service includes a connection of the same size to the NMS network. The Exchange has notified these 11 Users that their connections to the NMS feeds over LCN will be discontinued, and all 11 of them have submitted orders to begin receiving the NMS feeds over an NMS network connection at no additional charge. The Exchange is currently in the process of installing NMS network connections for those 11 Users.[8]

Users would experience no interruption in their ability to connect to the NMS feeds as a result of the proposed change, and would receive the NMS feeds faster as a result of the proposed change. No User would be required to purchase any additional products or services from the Exchange to transition their NMS feed connectivity to the NMS network, or to an IP network connection they have already purchased.

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally. The purchase of any colocation service is completely voluntary and the Price List and Fee Schedule is applied uniformly to all Users.

No fees are affected by this proposal.

Implementation Date

The Exchange is in the process of transitioning all remaining Users that receive the NMS feeds over the LCN to begin receiving the feeds over NMS network connections at no additional charge. The Exchange expects this transition process to be completed before October 2022. Once that transition is complete, the Exchange proposes to implement this rule change by Customer Notice, at which point the option of receiving the NMS feeds over the LCN would be removed from the Price List and Fee Schedule.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

[8] Seven of these 11 Users also currently have access to the IP network and could have chosen to receive the NMS feeds over their IP network connections at no additional charge, but instead all 11 have opted to receive the NMS feeds over the faster NMS network.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Users that currently receive the NMS feeds on the LCN would receive the same data at a faster speed via the NMS or IP network, with no interruption of their ability to connect to the NMS feeds. Connectivity to the NMS feeds over the NMS network would be available at no additional charge to affected Users, since their existing LCN service includes a connection of the same size to the NMS network. In addition, connectivity to the NMS feeds over the IP network would be at no additional charge to Users that have already purchased access to the IP network. The Exchange believes that providing connectivity to the same feeds at a faster speed at no additional charge would perfect the mechanisms of a free and open market and a national market system.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would simply give Users that currently receive the NMS feeds on the LCN the opportunity to receive the same data at a faster speed via the NMS network or the IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

The Exchange believes that discontinuing the availability of the

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

NMS feeds on the LCN would not permit unfair discrimination between customers, issuers, brokers, or dealers, because the proposed change would apply equally to all Users that currently receive the NMS feeds over the LCN. Nor does the proposed change advantage Users of the LCN over Users of the IP network, since, as indicated in the Price List and Fee Schedule, services that include a 10 Gb or 40 Gb LCN or IP connection also include a connection to the NMS network of the same size, at no additional charge.

The Exchange believes that the proposed change would facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because removing the NMS feeds from the LCN would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN. As noted above, increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements for the NYSE Group Market Data feeds over the LCN.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues, but rather would provide Users that currently receive the NMS feeds on the LCN the same data at a faster speed via the NMS or IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2022–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2022–28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2022–28 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15930 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95325; File No. SR–MEMX–2022–18]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Current Pilot Program Related to Clearly Erroneous Transactions Until October 20, 2022

July 20, 2022.

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 19, 2022, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to extend the current pilot program related to MEMX Rule 11.15, ''Clearly Erroneous Executions,'' to the close of business on October 20, 2022. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effectiveness of the Exchange's current rule applicable to Clearly Erroneous Executions to the close of business on October 20, 2022. Portions of Rule 11.15, explained in further detail below, are currently operating as a pilot program which is set to expire on July 20, 2022.[5]

On May 4, 2020, the Commission approved MEMX's Form 1 Application to register as a national securities exchange with rules including, on a pilot basis, MEMX Rule 11.15.[6] Rule 11.15, among other things (i) provides for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduces the ability of the Exchange to deviate from objective standards set forth in the rule. The rule further provides that: (i) a series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of the Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer of the Exchange or senior level employee designee, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security, and before such a trading halt has officially ended according to the primary listing market.[7]

Previously, the clearly erroneous pilot programs adopted by the national securities exchanges and the current Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'' or the ''LULD Plan'') were a single pilot program. On April 17, 2019, the Commission approved the Eighteenth Amendment to the LULD Plan, allowing the LULD Plan to operate on a permanent, rather than pilot, basis.[8] Accordingly, national securities exchanges filed with the Commission amendments to exchange rules to untie the pilot program's effectiveness from that of the LULD Plan in order to provide such exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules in light of the proposed Eighteenth Amendment to the LULD Plan.[9]

More recently, the Exchange amended MEMX Rule 11.15 to extend the pilot's effectiveness to the close of business on October 20, 2021.[10] The Exchange subsequently amended MEMX Rule 11.15 to extend the pilot's effectiveness to the close of business on April 20, 2022 [11] and again to extend the pilot's effectiveness to the close of business on July 20, 2022.[12]

On July 8, 2022, Cboe BZX Exchange, Inc. proposed a rule change to make the pilot program permanent with certain amendments.[13] The Exchange now proposes to amend MEMX Rule 11.15 to extend the pilot's effectiveness to the close of business on October 20, 2022, while the Commission considers whether the BZX proposal should be approved or disapproved. MEMX understands that certain other national securities exchanges and the Financial Industry Regulatory Authority (''FINRA'') also intend to file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to MEMX Rule 11.15.

The Exchange does not propose any additional changes to MEMX Rule 11.15. By proposing to extend the pilot, the Exchange will avoid any discrepancy between its clearly erroneous pilot program and the pilot programs of other exchanges and FINRA, as the language of such rules are identical to MEMX Rule 11.15 and, as noted above, other exchanges and FINRA also intend to file proposals to extend their respective clearly erroneous execution pilot programs. The Exchange believes the benefits to market

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* MEMX Rule 11.15.

[6] *See* Securities Exchange Release No. 88806 (May 4, 2020), 85 FR 27451 (May 8, 2020).

[7] *See* MEMX Rule 11.15.

[8] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (File No. 4–631).

[9] *See, e.g.,* Securities Exchange Act Release No. 85542 (April 8, 2019), 84 FR 15009 (April 12, 2019) (SR-CboeBYX–2019–003).

[10] *See* Securities Exchange Act Release No. 91457 (April 1, 2021), 86 FR 18082 (April 7, 2021) (SR–MEMX–2021–05).

[11] *See* Securities Exchange Act Release No. 93358 (October 15, 2021), 86 FR 58319 (October 21, 2021) (SR–MEMX–2021–13).

[12] *See* Securities Exchange Act Release No. 94684 (April 12, 2022), 87 FR 23006 (April 18, 2022) (SR–MEMX–2022–09).

[13] *See* Securities Exchange Act Release No. 95259 (July 12, 2022), 87 FR 42760 (July 18, 2022) (SR-CboeBZX–2022–037).

participants from the more objective clearly erroneous executions rule should continue on a limited three month pilot basis. As the LULD Plan was approved by the Commission to operate on a permanent, rather than pilot, basis the Exchange intends to assess whether additional changes should also be made to the operation of the clearly erroneous execution rules. Extending the effectiveness of MEMX Rule 11.15 for an additional three months should provide the Commission additional time to consider the recent proposal to make the pilot program permanent and any further amendments to the clearly erroneous execution rules.

Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to prevent fraudulent and manipulative practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that extending the clearly erroneous execution pilot under MEMX Rule 11.15 for an additional three months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed extension would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the clearly erroneous executions rule should continue to be in effect on a pilot basis while the Commission considers the pending proposal to make permanent the rules related to clearly erroneous executions reviews.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes its proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange understands that FINRA and certain other national securities exchanges will also file similar proposals to extend their respective clearly erroneous execution pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [16] and Rule 19b–4(f)(6) thereunder.[17] 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 Act [18] and subparagraph (f)(6) of Rule 19b–4 thereunder.[19]

A proposed rule change filed under Rule 19b–4(f)(6) [20] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[21] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30 day operative delay so that the proposal may become operative immediately upon filing. Waiver of the 30-day operative delay would extend the protections provided by the current pilot program, without any changes, while a permanent proposal for clearly erroneous execution reviews is being considered.[22] For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[23]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6).

[18] 15 U.S.C. 78s(b)(3)(A)(iii).

[19] 17 CFR 240.19b-4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has waived the five-day prefiling requirement in this case.

[20] 17 CFR 240.19b–4(f)(6).

[21] 17 CFR 240.19b–4(f)(6)(iii).

[22] *See* Securities Exchange Act Release No. 95259 (July 12, 2022), 87 FR 42760 (July 18, 2022) (SR-CboeBZX–2022–037).

[23] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–MEMX–2022–18 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–MEMX–2022–18. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2022–18 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15918 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95333; File No. SR–NYSENAT–2022–11]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make a Non-Substantive Change to Rule 7.31(a)(2)(B) Regarding Limit Order Price Protection

July 20, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 8, 2022, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make a non-substantive change to Rule 7.31(a)(2)(B) regarding Limit Order Price Protection. The proposed rule change is available on the Exchange's website 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 make a non-substantive change to Rule 7.31(a)(2)(B) regarding Limit Order Price Protection.

Rule 7.31(a)(2)(B) (''Limit Order Price Protection'') provides that a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of $0.15 or a specified percentage away from the National Best Offer (National Best Bid) (''NBO'' and ''NBB,'' respectively). The rule currently states that the ''specified percentage is equal to the corresponding 'numerical guideline' percentage set forth in paragraph (c)(1) of Rule 7.10 (Clearly Erroneous Executions) for the Core Trading Session.'' Pursuant to Rule 7.10(c)(1), those numerical guidelines are as follows: 10% for securities with a reference price up to and including $25.00, 5% for securities with a reference price greater than $25.00 and up to and including $50.00, and 3% for securities with a reference price greater than $50.00.

The Exchange proposes to amend Rule 7.31(a)(2)(B) to delete the cross-reference to Rule 7.10(c)(1) and instead include the specified percentages from Rule 7.10(c)(1) as a table in the text of Rule 7.31(a)(2)(B) itself, as follows:

Reference price	Specified percentage
Greater than $0.00 up to and including $25.00	10
Greater than $25.00 up to and including $50.00	5
Greater than $50.00	3

The Exchange does not propose any change to the percentages themselves or when they would apply. Accordingly, the proposed change would be non-substantive and would raise no novel issues.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and with Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change to Rule 7.31(a)(2)(B) would remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, protect investors and the public interest because deleting the cross-reference to Rule 7.10(c)(1) and instead including the relevant percentages from Rule 7.10(c)(1) in the text of Rule 7.31(a)(2)(B) itself will enhance the clarity of the rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather would be a non-substantive change to delete the cross-reference to Rule 7.10(c)(1) and instead include the relevant percentages from Rule 7.10(c)(1) in the text of Rule 7.31(a)(2)(B) itself.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

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 Act[6] and Rule 19b–4(f)(6)[7] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtm*l); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2022–11 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–NYSENAT–2022–11. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2022–11 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15925 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A).

[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.

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95336; File No. SR–NYSECHX–2022–16]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make a Non-Substantive Change to Rule 7.31(a)(2)(B) Regarding Limit Order Price Protection

July 20, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 8, 2022, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make a non-substantive change to Rule 7.31(a)(2)(B) regarding Limit Order Price Protection. The proposed rule change is available on the Exchange's website 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 make a non-substantive change to Rule 7.31(a)(2)(B) regarding Limit Order Price Protection.

Rule 7.31(a)(2)(B) (''Limit Order Price Protection'') provides that a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of $0.15 or a specified percentage away from the National Best Offer (National Best Bid) (''NBO'' and ''NBB,'' respectively). The rule currently states that the ''specified percentage is equal to the corresponding 'numerical guideline' percentage set forth in paragraph (c)(1) of Rule 7.10 (Clearly Erroneous Executions) for the Core Trading Session.'' Pursuant to Rule

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

7.10(c)(1), those numerical guidelines are as follows: 10% for securities with a reference price up to and including $25.00, 5% for securities with a reference price greater than $25.00 and up to and including $50.00, and 3% for securities with a reference price greater than $50.00.

The Exchange proposes to amend Rule 7.31(a)(2)(B) to delete the cross-reference to Rule 7.10(c)(1) and instead include the specified percentages from Rule 7.10(c)(1) as a table in the text of Rule 7.31(a)(2)(B) itself, as follows:

Reference price	Specified percentage
Greater than $0.00 up to and including $25.00	10
Greater than $25.00 up to and including $50.00	5
Greater than $50.00	3

The Exchange does not propose any change to the percentages themselves or when they would apply. Accordingly, the proposed change would be non-substantive and would raise no novel issues.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and with Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change to Rule 7.31(a)(2)(B) would remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, protect investors and the public interest because deleting the cross-reference to Rule 7.10(c)(1) and instead including the relevant percentages from Rule 7.10(c)(1) in the text of Rule 7.31(a)(2)(B) itself will enhance the clarity of the rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather would be a non-substantive change to delete the cross-reference to Rule 7.10(c)(1) and instead include the relevant percentages from Rule 7.10(c)(1) in the text of Rule 7.31(a)(2)(B) itself.

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 Act[6] and Rule 19b–4(f)(6)[7] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSECHX–2022–16 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–NYSECHX–2022–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSECHX–2022–16 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15928 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A).

[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.

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95332; File No. SR–BX–2022–011]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Clearly Erroneous Pilot to October 20, 2022

July 20, 2022.

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 19, 2022, Nasdaq BX, Inc. (''BX'' 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 extend the current pilot program related to BX Equity 11, Rule 11890 (Clearly Erroneous Transactions) to the close of business on October 20, 2022.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* 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 extend the current pilot program related to Equity 11, Rule 11890, Clearly Erroneous Transactions, to the close of business on October 20, 2022. The pilot program is currently due to expire on July 20, 2022.

On September 10, 2010, the Commission approved, on a pilot basis, changes to Equity 11, Rule 11890 that, among other things: (i) provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[3] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[4] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) a series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[5]

These changes were originally scheduled to operate for a pilot period to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or ''LULD Plan'').[6] In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[7] In light of that change, the Exchange amended Equity 11, Rule 11890 to untie the pilot program's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[8] Subsequently, the Exchange amended Rule 11890 to extend the pilot's effectiveness to the close of business on July 20, 2022.[9]

The Exchange now proposes to amend Equity 11, Rule 11890 to extend the pilot's effectiveness for a further three months until the close of business on October 20, 2022. If the pilot period is not either extended, replaced or approved as permanent, the prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) shall be in effect, and the provisions of paragraphs (g) through (i) shall be null and void.[10] In such an event, the remaining sections of Rule 11890 would continue to apply to all transactions executed on the Exchange. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to Rule 11890.

The Exchange does not propose any additional changes to Equity 11, Rule 11890. Extending the effectiveness of Rule 11890 for an additional three months will provide the Exchange and other self-regulatory organizations additional time to consider whether further amendments to the clearly erroneous execution rules are appropriate.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[11] in general, and Section 6(b)(5) of the Act,[12] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–BX–2010–040).

[4] *See* Securities Exchange Act Release No. 68818 (February 1, 2013), 78 FR 9100 (February 7, 2013) (SR–BX–2013–010).

[5] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–BX–2014–021).

[6] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[7] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (approving Eighteenth Amendment to LULD Plan).

[8] *See* Securities Exchange Act Release No. 85613 (April 11, 2019), 84 FR 16077 (April 17, 2019) (SR–BX–2019–009).

[9] *See* Securities Exchange Act Release No. 94761 (April 20, 2022), 87 FR 24595 (April 26, 2022) (SR–BX–2022–008).

[10] *See* notes 3–5, *supra*. The prior versions of paragraphs (a)(2)(C), (c)(1), (b)(i), and (b)(ii) generally provided greater discretion to the Exchange with respect to breaking erroneous trades.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

across markets concerning review of transactions as clearly erroneous. The Exchange believes that extending the clearly erroneous execution pilot under Equity 11, Rule 11890 for an additional three months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal would ensure the continued, uninterrupted operation of harmonized clearly erroneous execution rules across the U.S. equities markets while the Exchange and other self-regulatory organizations consider whether further amendments to these rules are appropriate. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals to extend their respective clearly erroneous execution pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [13] and Rule 19b–4(f)(6) thereunder.[14] 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 Act [15] and subparagraph (f)(6) of Rule 19b–4 thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6) [17] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[18] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30 day operative delay so that the proposal may become operative immediately upon filing. Waiver of the 30-day operative delay would extend the protections provided by the current pilot program, without any changes, while a permanent proposal for clearly erroneous execution reviews is being considered.[19] For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[20]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2022–011 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–BX–2022–011. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2022–011 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15924 Filed 7–25–22; 8:45 am]

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[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] *See* Securities Exchange Act Release No. 95259 (July 12, 2022), 87 FR 42760 (July 18, 2022) (SR–CboeBZX–2022–037).

[20] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95339; File No. SR–NYSEArca–2022–39]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges and the NYSE Arca Options Fees and Charges Related to Colocation

July 20, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 6, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges and the NYSE Arca Options Fees and Charges (together, the ''Fee Schedules'') related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN''). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedules related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN'').[4]

Background

The LCN and the IP network are the two local area networks in the Mahwah Data Center that are available to Users.[5] General Note 5 of the Fee Schedules explains that when a User purchases a service that includes access to the LCN or IP network, it receives connectivity to any of the ''Included Data Products'' that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. The Included Data Products include, among others, the ''NMS feeds,'' which are the Consolidated Tape System and Consolidated Quote System (''CTA'' and ''CQ,'' respectively) data feeds and the Options Price Reporting Authority (''OPRA'') data feed.[6]

Before May 2020, connectivity to the NMS feeds was available on only the LCN and IP networks. In May 2020, the Commission approved the Exchange's proposal to offer Users access to the new ''NMS network,'' an alternate, dedicated network that connects to the NMS feeds faster than the LCN or IP networks.[7] Pursuant to that filing, the Exchange amended the notes regarding the services available in colocation to provide that if a User purchases a service that includes a 10 Gb or 40 Gb LCN or IP network connection, that service would also include a connection to the NMS network of the same size, at no additional charge.

Currently, the NMS feeds are available to Users on all three of the NMS network, IP network, and LCN, but at varying speeds. The NMS feeds are published first to the NMS network, which then republishes them to the IP network, which then republishes them to the LCN. This means that connectivity to the NMS feeds is fastest over the NMS network and slowest over the LCN. This also means that receiving the NMS feeds from more than one of these networks does not provide redundancy protection to Users; if connectivity to the NMS feeds over the NMS network were to be interrupted, so would connectivity to those feeds over the IP network and LCN, since the three networks publish the NMS feeds to each other in sequence.

Despite the Exchange's introduction of the NMS network in May 2020, some Users have failed to avail themselves of the option to receive the NMS feeds over that faster network at no additional cost. Other Users have opted to receive the NMS feeds over the NMS network, but have not yet formally asked the Exchange to stop also sending them the NMS feeds over the other networks (*i.e.,* IP network or LCN) for which those Users have ports.

At the same time, traffic over the LCN has been increasing. Increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements overall for the market data feeds of the Exchange and the Affiliate SROs that are included in the Included Data Products (the ''NYSE Group Market Data'' feeds) over the LCN. As a result, the LCN connections over which some Users continue to receive the NMS feeds are increasingly burdened as the NYSE Group Market Data Feeds continue to grow in size.

To address these issues, the Exchange proposes to remove the NMS feeds from the Included Data Products available on the LCN. Doing so would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN.

To accomplish this change, the Exchange proposes to amend General

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs'') has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2022–27, SR–NYSEAMER–2022–28, SR–NYSECHX–2022–15, and SR–NYSENAT–2022–10.

[5] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76101 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the Fee Schedules, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[6] *See* Securities Exchange Act Release No. 79729 (January 4, 2017), 82 FR 3061 (January 10, 2017) (SR–NYSEArca–2016–172).

[7] *See* Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR–NYSEArca–2019–61, SR–NYSENAT–2019–19). *See also* Securities Exchange Act Release No. 88972 (May 29, 2020), 85 FR 34472 (June 4, 2020) (SR–NYSECHX–2020–18).

Note 5 of the Fee Schedules as follows (proposed addition italicized):

5. When a User purchases a service that includes access to the LCN or IP network it receives connectivity to any of the Included Data Products that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. *Connectivity to the NMS feeds is not available over the LCN, but is available over the IP network and the NMS network described below in General Note 6.* Market data fees for the Included Data Products are charged by the provider of the data feed. A User can change the Included Data Products to which it receives connectivity at any time, subject to authorization from the provider of the data feed. The Exchange is not the exclusive method to connect to the Included Data Products.

Application and Impact of the Proposed Changes

Currently, 34 Users receive the NMS feeds over the LCN, but 23 of those 34 Users have access to the NMS network already enabled, such that they also receive the NMS feeds over the NMS network. To implement this proposal with respect to those 23 Users, the Exchange has notified the Users that their connections to the NMS feeds over LCN will be discontinued but that they will continue to receive the NMS feeds over the NMS network.

The other 11 Users that receive the NMS feeds over the LCN do not currently have NMS network access enabled, but are entitled to such access at no additional charge, since their existing LCN service includes a connection of the same size to the NMS network. The Exchange has notified these 11 Users that their connections to the NMS feeds over LCN will be discontinued, and all 11 of them have submitted orders to begin receiving the NMS feeds over an NMS network connection at no additional charge. The Exchange is currently in the process of installing NMS network connections for those 11 Users.[8]

Users would experience no interruption in their ability to connect to the NMS feeds as a result of the proposed change, and would receive the NMS feeds faster as a result of the proposed change. No User would be required to purchase any additional products or services from the Exchange to transition their NMS feed connectivity to the NMS network, or to an IP network connection they have already purchased.

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally. The purchase of any colocation service is completely voluntary and the Fee Schedules are applied uniformly to all Users.

No fees are affected by this proposal.

Implementation Date

The Exchange is in the process of transitioning all remaining Users that receive the NMS feeds over the LCN to begin receiving the feeds over NMS network connections at no additional charge. The Exchange expects this transition process to be completed before October 2022. Once that transition is complete, the Exchange proposes to implement this rule change by Customer Notice, at which point the option of receiving the NMS feeds over the LCN would be removed from the Fee Schedules.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Users that currently receive the NMS feeds on the LCN would receive the same data at a faster speed via the NMS or IP network, with no interruption of their ability to connect to the NMS feeds. Connectivity to the NMS feeds over the NMS network would be available at no additional charge to affected Users, since their existing LCN service includes a connection of the same size to the NMS network. In addition, connectivity to the NMS feeds over the IP network would be at no additional charge to Users that have already purchased access to the IP network. The Exchange believes that providing connectivity to the same feeds at a faster speed at no additional charge would perfect the mechanisms of a free and open market and a national market system.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would simply give Users that currently receive the NMS feeds on the LCN the opportunity to receive the same data at a faster speed via the NMS network or the IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would not permit unfair discrimination between customers, issuers, brokers, or dealers, because the proposed change would apply equally to all Users that currently receive the NMS feeds over the LCN. Nor does the proposed change advantage Users of the LCN over Users of the IP network, since, as indicated in the Fee Schedules, services that include a 10 Gb or 40 Gb LCN or IP connection also include a connection to the NMS network of the same size, at no additional charge.

The Exchange believes that the proposed change would facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because removing the NMS feeds from the LCN would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN. As noted above, increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the

[8] Seven of these 11 Users also currently have access to the IP network and could have chosen to receive the NMS feeds over their IP network connections at no additional charge, but instead all 11 have opted to receive the NMS feeds over the faster NMS network.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

market data feeds from those markets, thereby increasing the network bandwidth requirements for the NYSE Group Market Data feeds over the LCN.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues, but rather would provide Users that currently receive the NMS feeds on the LCN the same data at a faster speed via the NMS or IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2022–39 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2022–39. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the 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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2022–39 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15931 Filed 7–25–22; 8:45 am]

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[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95343; File No. SR–EMERALD–2022–24]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 515 To Make Minor, Non-Substantive Edits

July 20, 2022.

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 18, 2022, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 make a number of minor, non-substantive edits to Exchange Rule 515, Execution of Orders and Quotes.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxoptions.com/rule-filings/emerald,* at MIAX Emerald's

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 515 to make minor, non-substantive edits and clarifying changes to provide accuracy, precision, and ease of reference within the rule text.

First, the Exchange proposes to amend current subparagraph (a) to add the word ''the'' at the end of the last sentence in the first paragraph for grammatical correctness and clarity in the Rule text. Accordingly, with the proposed change, the last sentence in the first paragraph of subparagraph (a) will read as follows: ''Orders and quotes that could not be executed because the executions would be at prices inferior to the NBBO will be handled in accordance with the Managed Interest Process for orders described in paragraph (c)(1)(ii) below or in accordance with the process for handling Market Maker orders and quotes described in paragraph (d) below.''

The Exchange also proposes to amend several paragraphs and subsections to make corrective changes to the numerical and alphabetical list item identifiers to properly conform to the hierarchical heading scheme and list item identifiers used throughout the Exchange's rulebook. The Exchange notes that anytime there is block text in a paragraph or subsection that contains a list of numbered clauses or items that are not specifically broken out into their own subsections, the Exchange uses romanettes to identify each clause or item. Accordingly, the Exchange proposes to amend current subparagraph (h)(3) of Exchange Rule 515 that contains independent clauses currently numbered ''(A)'' through ''(D)'' to now be renumbered ''(i)'' through ''(iv)'', respectively. The Exchange also proposes to amend current subparagraph (h)(4) that contains independent clauses currently numbered ''(A)'', ''(B)'', and ''(C)'' to now be renumbered to ''(i)'', ''(ii)'', and ''(iii)'', respectively. The purpose of all these proposed changes is to promote consistency and clarity within the Exchange's Rulebook and conform to the existing identification scheme.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Act [3] in general, and furthers [sic] the objectives of Section 6(b)(5) of the Act [4] in particular, in that they are designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanisms [sic] of a free and open market and a national market system and, in general, protect investors and the public interest.

The Exchange believes the proposed changes to Exchange Rule 515 promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule changes will provide greater clarity to Members [5] and the public regarding the Exchange's Rules by correcting a grammatical error and conforming the numbering in Exchange Rule 515 to the existing identification scheme in the Exchange's rulebook. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition as there is no functional change to the Exchange's System [6] and because the rules of the Exchange apply to all MIAX Emerald participants equally. The Exchange believes the proposed rule changes will have [sic] not impose any burden on intra-market competition as the proposed changes are not designed to address any competitive issue but rather are designed to remedy minor non-substantive issues and provide added precision and accuracy to the rule text of Exchange Rule 515. In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal does not address any competitive issues and is intended to protect investors by providing further transparency and precision for referencing the Exchange's Rules.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [7] and Rule 19b–4(f)(6) [8] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

[5] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[6] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EMERALD–2022–24.

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–EMERALD–2022–24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the 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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EMERALD–2022–24, and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15935 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95327; File No. SR–OCC–2022–803]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Advance Notice Related to an Expansion of The Options Clearing Corporation's Non-Bank Liquidity Facility Program as Part of Its Overall Liquidity Plan

July 20, 2022.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled Payment, Clearing and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) [2] under the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[3] notice is hereby given that on July 7, 2022, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') an advance notice as described in Items I, II and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This advance notice is submitted in connection with a proposed change to its operations to expand capacity under OCC's program for accessing additional committed sources of liquidity that do not increase the concentration of OCC's counterparty exposure (''Non-Bank Liquidity Facility'') as part of OCC's overall liquidity plan. The proposed changes do not require any changes to the text of OCC's By-Laws or Rules. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[4]

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 15 U.S.C. 78a *et seq.*

[4] OCC's By-Laws and Rules can be found on OCC's public website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A) and (B) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the advance notice and none have been received. OCC will notify the Commission of any written comments received by OCC.

(B) Advance Notices Filed Pursuant to Section 806(e) of the Payment, Clearing, and Settlement Supervision Act

Description of Change

As the sole clearing agency for standardized U.S. securities options listed on national securities exchanges registered with the Commission (''listed options''), OCC is obligated to make certain payments. In the event of a Clearing Member default, OCC would be obligated to make payments, on time, related to that member's clear transactions. To meet such payment obligations, OCC maintains access to cash from a variety of sources, including, a requirement for members to pledge cash collateral to OCC and various agreements with banks and other counterparties (''liquidity facilities'') to provide OCC with cash in exchange for collateral, such as U.S. Government securities. OCC routinely considers potential market stress scenarios that could affect such payment obligations. Based on such considerations, OCC now believes that it should seek to expand its liquidity facility to increase OCC's access to cash to manage a member default.

OCC is proposing to expand the size of its liquidity facilities by increasing the size of one of its liquidity facilities. Specifically, this advance notice concerns a change to OCC's operations to expand capacity under OCC's Non-Bank Liquidity Facility as part of OCC's overall liquidity plan, which includes OCC's arrangements to access cash in exchange for Government securities deposited by Clearing Members in respect of their Clearing Fund

requirements to meet OCC's settlement obligations. OCC is not, as part of this advance notice, proposing to require its members or other market participants provide additional or different collateral to OCC. Rather, the purpose of the proposal is to provide OCC with another vehicle for accessing cash to meet its payment obligations, including in the event that one of its members fails to meet its payment obligations to OCC.[5]

Background

OCC's current liquidity plan provides it with access to a diverse set of funding sources, including banks (*i.e.,* OCC's syndicated credit facility),[6] the Non-Bank Liquidity Facility program,[7] and Clearing Members' Cash Clearing Fund Requirement.[8] The Non-Bank Liquidity Facility program reduces the concentration of OCC's counterparty exposure with respect to its overall liquidity plan by diversifying its base of liquidity providers among banks and non-bank, non-Clearing Member institutional investors, such as pension funds or insurance companies.

The currently approved Non-Bank Liquidity Facility program is comprised of two parts: a Master Repurchase Agreement (''MRA'') and confirmations with one or more institutional investors, which contain certain individualized terms and conditions of transactions executed between OCC, the institutional investors and their agents. The MRA is structured like a typical repurchase arrangement in which the buyer (*i.e.,* the institutional investor) would purchase from OCC, from time to time, Government securities (''Eligible Securities'').[9] OCC, as the seller, would transfer Eligible Securities to the buyer in exchange for a payment by the buyer to OCC in immediately available funds (''Purchase Price''). The buyer would simultaneously agree to transfer the purchased securities back to OCC at a specified later date (''Repurchase Date'') or on OCC's demand against the transfer of funds by OCC to the buyer in an amount equal to the outstanding Purchase Price plus the accrued and unpaid price differential (together, ''Repurchase Price''), which is the interest component of the Repurchase Price.

The confirmations establish tailored provisions of repurchase transactions permitted under the Non-Bank Liquidity Facility that are designed to reduce concentration risk and to promote certainty of funding and operational effectiveness based on the specific needs of a party. For example, OCC would only enter into confirmations with an institutional investor that is not a Clearing Member or affiliated bank, such as pension funds or insurance companies, in order to allow OCC to access stable and reliable sources of funding without increasing the concentration of its exposure to counterparties that are affiliated banks, broker/dealers, or futures commission merchants. In addition, any such institutional investor is obligated to enter repurchase transactions even if OCC experiences a material adverse change,[10] funds must be made available to OCC within 60 minutes of OCC's delivering eligible securities, and the institutional investor is not permitted to rehypothecate purchased securities.[11] Additionally, the confirmations set forth the term and maximum dollar amounts of the transaction permitted under the MRA.

In 2020, OCC set the aggregate amount it may seek through the Non-Bank Liquidity Facility program to an amount up to $1 billion.[12] OCC has since secured from multiple pension funds commitments in an aggregate amount of $1 billion. Since setting and securing commitments up to that aggregate commitment limit, OCC has experienced an increase in its stressed liquidity demands. Under OCC's Liquidity Risk Management Framework (''LRMF''), OCC performs daily liquidity stress testing to assess its Base Liquidity Resources[13] and Available Liquidity Resources[14] against OCC's liquidity risk tolerance (''Adequacy Scenarios''). Based in part on the results of this stress testing, OCC's Rules provide authority for OCC to periodically adjust Clearing Member's Cash Clearing Fund Requirement to ensure that OCC maintains sufficient liquidity resources to cover its liquidity risk exposures at all times. In response to increased stressed liquidity demands in 2021, OCC exercised authority under OCC Rule 1002(a) to increase the Cash Clearing Fund Requirement from $3.5 billion to $4 billion in July 2021, and from $4 billion to $5 billion in October 2021. This advance notice concerns a change to OCC's Non-Bank Liquidity Facility program to give OCC greater capacity to source liquidity from its non-bank liquidity providers as needed. OCC provided a summary of OCC management's recommendation to expand OCC's external liquidity sources as well as a discussion of the analysis underlying that recommendation as presented to the Board in confidential Exhibit 3 to File No. SR–OCC–2022–803.

Proposed Change

In order to give OCC greater capacity to source liquidity from external liquidity providers as needed, OCC would modify the Non-Bank Liquidity Facility program to remove the aggregate commitment limit identified in prior advance notices concerning the program. Instead, OCC's Board of Directors by resolution would set the level of aggregate commitments under the program from time to time to ensure that OCC maintains sufficient liquidity

[5] OCC may use the Clearing Fund to address liquidity shortfalls arising from the failure of any bank, securities or commodities clearing organization, or investment counterparty to perform any obligation to OCC when due. *See* OCC Rule 1006(f)(1)(C); Exchange Act Release No. 94304 (Feb. 24, 2022), 87 FR 11776 (Mar. 2, 2022) (SR–OCC–2021–014).

[6] *See* Exchange Act Release No. 88971 (May 28, 2020), 85 FR 34257 (June 3, 2020) (SR–OCC–2020–804).

[7] *See* Exchange Act Release No. 89039 (June 10, 2020), 85 FR 36444 (June 16, 2020) (SR–OCC–2020–803) (''Notice of No Objection to 2020 Advance Notice''); Exchange Act Release No. 76821 (Jan. 4, 2016), 81 FR 3208 (Jan. 20, 2016) (SR–OCC–2015–805) (''Notice of No Objection to 2015 Advance Notice''); Exchange Act Release No. 73979 (Jan. 2, 2015), 80 FR 1062 (Jan. 8, 2015) (SR–OCC–2014–809) (''Notice of No Objection to 2014 Advance Notice'').

[8] *See* OCC Rule 1002.

[9] OCC would use U.S. government securities that are included in Clearing Fund contributions by Clearing Members and margin deposits of any Clearing Member that has been suspended by OCC for the repurchase arrangements. OCC Rule 1006(f) and OCC Rule 1104(b) authorize OCC to obtain funds from third parties through securities repurchases using these sources. The officers who may exercise this authority include the Executive Chairman, Chief Executive Officer, and Chief Operating Officer.

[10] When included in a contract, a ''material adverse change'' is typically defined as a change that would have a materially adverse effect on the business or financial condition of a company.

[11] *See* Notice of No Objection to 2014 Advance Notice, 80 FR at 1064.

[12] *See* Notice of No Objection to 2020 Advance Notice, 85 FR at 36446. $1 billion is the same as the aggregate value established at the inception of the Non-Bank Liquidity Facility program. *See* Notice of No Objection to 2014 Advance Notice, 80 FR at 1064 & n.11. In 2015, OCC filed an advance notice that set an aggregate value of at least $1 billion and up to $1.5 billion. *See* Notice of No Objection to 2015 Advance Notice, 81 FR at 3208.

[13] The LRMF defines ''Base Liquidity Resources'' to mean the amount of committed liquidity resources maintained at all times by OCC to meet its Cover 1 liquidity resource requirements under the applicable regulations. Base Liquidity Resources are comprised of qualifying liquid resources in the form of Clearing Fund cash deposited in respect of the Cash Clearing Fund Requirement and assets that are readily available and convertible into cash (*i.e.,* Government securities) through prearranged funding arrangements, such as the Non-Bank Liquidity Facility.

[14] The LRMF defines ''Available Liquidity Resources'' to include Base Liquidity Resources plus allowable Clearing Fund cash deposited in excess of the Cash Clearing Fund Requirement. Any Clearing Member request to substitute Government securities for cash deposits in excess of such Clearing Member's propitiate share of the Clearing Fund Cash Requirement is subject to a two-day notice period. *See* OCC Rule 1002(a)(iv).

resources to cover its liquidity risk exposures at all times considering such factors including, but not limited to: (1) the size and make-up of the Clearing Fund; (2) the aggregate amount of OCC's other liquidity sources; and (3) changing market and business conditions. OCC would establish a target across all external liquidity resources of *at least* $3 billion, which is the current aggregate amount of external liquidity. OCC would continue to manage the allocation between external liquidity sources to maintain a diverse set of liquidity providers, including sources like the Non-Bank Liquidity Facility that reduce concentration of OCC's counterparty exposures.

Considering these factors, the Board of Directors has authorized OCC to seek up to an additional $2.5 billion in external liquidity, including through the Non-Bank Liquidity Facility program. Specifically, the Board considered that:

(1) OCC's current total Clearing Fund requirement, as of January 31, 2022, was approximately $15.8 billion, of which Clearing Members had deposited approximately $5.5 billion in Government securities.

(2) OCC's Base Liquidity Resources are currently $8 billion, consisting of $5 billion in cash from the Clearing Fund Cash Requirement, $2 billion from the syndicated credit facility, and $1 billion from OCC's current commitments under the Non-Bank Liquidity Facility.

(3) The agent for the liquidity providers under Non-Bank Liquidity Facility has indicated that several pension funds and other institutional investors have expressed interest in establishing or expanding commitments under the facility.[15]

OCC expects that it will source up to $500 million of this liquidity through an expansion of the syndicated credit facility as part of its annual renewal in June.[16] In addition, OCC concurrently has filed an advance notice to source liquidity through a bank counterparty by executing another master repurchase agreement for up to $1 billion (the ''Bank Repo Facility''), similar to the repurchase agreement OCC executed with a bank counterparty in 2020,[17] this time with a bank counterparty to which OCC has more limited counterparty credit exposure. Accordingly, OCC expects to source approximately $1 billion in additional liquidity under the Non-Bank Liquidity Facility. As such, the proportion of bank versus non-bank sources of liquidity would remain roughly equal to the current proportions, consistent with OCC's objective to maintain access to a diverse set of funding sources. However, to the extent that commitments under the syndicated credit facility or master repurchase agreement with a bank counterparty are less than anticipated, the Board has authorized OCC to seek additional commitments under the Non-Bank Liquidity Facility program to make up any difference. In the unlikely event that OCC is not able to onboard any of the additional bank liquidity and sources the full $2.5 billion under the Non-Bank Liquidity Facility program, OCC believes that the change in proportions between bank and non-bank liquidity would still be consistent with OCC's objective to maintain access to a diverse set of funding sources. Based on current interest received from potential counterparties, OCC believes that the risk that OCC would not be able to obtain $2.5 billion in additional external liquidity through one of more of these sources of liquidity to be low.

Removing the present $1 billion dollar cap to the Non-Bank Liquidity Facility program will also have the effect of removing one of the events in which OCC would file an advance notice for entering into individual commitments that OCC identified in a prior advance notice.[18] Consistent with the proposal to establish a target for external liquidity and drawing from applicable conditions for filing advance notices with respect to renewals of OCC's syndicated credit facility and proposed Bank Repo Facility, OCC would submit another advance notice with respect to the execution of individual commitments under the Non-Bank Liquidity Facility only if: (i) OCC should seek to execute a commitment at a level that would have the effect of reducing external liquidity below the target of $3 billion; (ii) OCC should seek to change the terms and conditions of the MRA or commitments thereunder in a manner that materially affects the nature or level of risk presented by OCC;[19] or (iii) OCC should seek to execute a commitment with a counterparty that has experienced a negative change to its credit profile or a material adverse change since OCC last executed a commitment with that counterparty. Consistent with another prior advance notice, OCC may consider changes to (i) liquidity providers provided that any new counterparty is subject to a credit review under OCC's Third-Party Risk Management Framework[20] and (ii) term lengths consistent with those approved by OCC's Board considering factors including, but not limited to, the initial committed length of the term, market conditions, and OCC's liquidity needs.[21] OCC would not consider additional counterparties or different commitment terms within these specified parameters as materially altering the terms and conditions of MRAs or commitments under the Non-Bank Liquidity Facility program.

Provided that none of the conditions under which OCC would file a subsequent advance notice are present, OCC would consider a new or renewed commitment as being on substantially the same terms and conditions as existing commitments under the Non-Bank Liquidity Facility program such that executing such commitments would not be subject to the requirement to file an advance notice filing pursuant to Section 806(e)(1) of the Clearing Supervision Act.[22] If OCC determines to modify the conditions for a new or renewed commitment under the Non-Bank Liquidity Facility in a subsequent filing, it would include in that filing the proposed conditions to the terms of any subsequent commitments or renewals

[15] *See* Confidential Exhibit 3 to SR–OCC–2022–803 (Confidential data and analysis that informed the Board's decision).

[16] *See* Exchange Act Release No. 88971, 85 FR at 34259 (providing conditions for future renewals of the syndicated credit facility without an additional advance notice, including an increase of up to $500 million in total).

[17] *See* Exchange Act Release No. 88317 (Mar. 4, 2020), 85 FR 13681 (Mar. 9, 2020) (SR–OCC–2020–801) (concerning the establishment of a ''Bank Repo Facility'' with a bank counterparty in an amount of $500 million).

[18] *See* Exchange Act Release No. 76821, 81 FR at 3209 (describing OCC's proposal to submit an advance notice in connection with a renewal of commitments under the Non-Bank Liquidity Facility if: (i) OCC determined that its liquidity needs merited commitments above or below certain levels; (ii) OCC should seek to change the terms and conditions of the Non-Bank Liquidity Facility; and (iii) the commitment counterparty experienced a negative change to its credit profile or a material adverse change since entering the commitment or the latest renewal of the commitment). OCC subsequently submitted an advance notice pursuant to that commitment to support its ability to onboard multiple liquidity providers below the identified commitment levels and with different term lengths to replace expiring commitments. *See* Exchange Act Release No. 89039, 85 FR at 36445–46.

[19] For the purposes of clarity, OCC would not consider changes to pricing or changes in representations, covenants, and terms of events of default, to be changes to a term or condition that would require the filing of a subsequent advance notice provided that pricing is at the then prevailing market rate and changes to such other provisions are immaterial to OCC as the seller and do not impair materially OCC's ability to draw against the facility.

[20] *See* Third-Party Risk Management Framework, *available at* Documents & Archives, *https://www.theocc.com/Company-Information/Documents-and-Archives.* While credit monitoring of insurance companies that may become liquidity providers would necessarily be different than credit monitoring of existing pension fund counterparties, any new liquidity would be subject to the same credit review for counterparties of the same type.

[21] *See* Exchange Act Release No. 89039, 85 FR at 36445–46.

[22] 12 U.S.C. 5465(e)(1).

that could be done without an additional advance notice.

Anticipated Effect On and Management of Risk

Completing timely settlement is a key aspect of OCC's role as the clearing agency performing central counterparty services for all listed options. Expanding the Non-Bank Liquidity Facility program would continue to promote the reduction of risks to OCC, its Clearing Members and the options market in general because it would allow OCC to obtain short-term funds from the Non-Bank Liquidity Facility to address liquidity demands arising out of the default or suspension of a Clearing Member, in anticipation of a potential default or suspension of Clearing Members, the insolvency of a bank, another securities or commodities clearing organization, or a counterparty with which OCC has invested Clearing Member funds, or the failure of such a bank clearing organization, or investment counterparty to meet an obligation to OCC when due.

The Non-Bank Liquidity Facility helps OCC minimize losses in the event of a default, suspension, insolvency, or failure to achieve daily settlement, by allowing it to obtain funds from sources not connected to OCC's Clearing Members on extremely short notice to ensure clearance and settlement of transactions in options and other contracts without interruption. OCC believes that the reduced settlement risk presented by OCC resulting from the proposed change would correspondingly reduce systemic risk and promote the safety and soundness of the clearing system. The ability to borrow funds from the Non-Bank Liquidity Facility would allow OCC to avoid liquidating margin or clearing fund assets in what would likely be volatile market conditions, which would preserve funds available to cover any losses resulting from the failure of a Clearing Member, bank, other clearing organization, or investment counterparty.

The proposed change to the Non-Bank Liquidity Facility program to allow OCC to seek an aggregate commitment amount for up to the amount determined by the Board of the Directors from time to time would help OCC ensure the continued availability of its liquidity resources by providing OCC with the capacity to seek additional funding amounts on substantially the same terms, conditions, operations, and mechanics. In addition, the proposed change to the program would ensure that the approved amount would not be less than the currently approved amount of up to $1 billion. Because the proposed change preserves substantially the same terms and conditions as the MRA and the existing conformations, OCC believes that the proposed change would not otherwise affect or alter the management of risk at OCC.

Consistency With the Payment, Clearing and Settlement Supervision Act

The stated purpose of the Clearing Supervision Act is to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[23] Section 805(a)(2) of the Clearing Supervision Act [24] also authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities, like OCC, for which the Commission is the supervisory agency. Section 805(b) of the Clearing Supervision Act [25] states that the objectives and principles for risk management standards prescribed under Section 805(a) shall be to:

- promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.

The Commission has adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act and the Exchange Act in furtherance of these objectives and principles.[26] Rule 17Ad–22 requires registered clearing agencies, like OCC, to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[27] Therefore, the Commission has stated [28] that it believes it is appropriate to review changes proposed in advance notices against Rule 17Ad–22 and the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act.[29]

OCC believes that the Non-Bank Liquidity Facility program, as modified, is consistent with Section 805(b)(1) of the Clearing Supervision Act [30] because the proposed confirmations would provide OCC with an additional source of committed liquidity to meet its settlement obligations while at the same time being structured to mitigate certain operational risks, as described above, that arise in connection with this committed liquidity source. In this way, the proposed changes are designed to promote robust risk management; promote safety and soundness; reduce systemic risks; and support the stability of the broader financial system.

OCC believes that the Non-Bank Liquidity Facility program, as modified, is also consistent with the requirements of Rule 17Ad–22(e)(7) under the Exchange Act.[31] Rule 17Ad–22(e)(7) requires OCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively measure, monitor, and manage liquidity risk that arises in or is borne by OCC, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity, as specified in the rule.[32] In particular, Rule 17Ad–22(e)(7)(i) under the Exchange Act [33] directs that OCC meet this obligation by, among other things, ''[m]aintaining sufficient liquid resources at the minimum in all relevant currencies to effect same-day . . . settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios that includes, but is not limited to, the default of the participant family that would generate the largest aggregate payment obligation for [OCC] in extreme but plausible market conditions.''

As described above, the proposed change would allow OCC to seek a readily available liquidity resource that would enable it to, among other things, continue to meet its obligations in a timely fashion and as an alternative to selling Clearing Member collateral under what may be stressed and volatile market conditions. For these reasons, OCC believes that the proposal is consistent with Rule 17Ad–22(e)(7)(i).[34]

Rule 17Ad–22(e)(7)(ii) under the Exchange Act requires OCC to establish,

[23] 12 U.S.C. 5461(b).

[24] 12 U.S.C. 5464(a)(2).

[25] 12 U.S.C. 5464(b).

[26] 17 CFR 240.17Ad-22. *See* Exchange Act Release Nos. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11) (''Clearing Agency Standards''); 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (''Standards for Covered Clearing Agencies'').

[27] 17 CFR 240.17Ad–22.

[28] *See, e.g.,* Exchange Act Release No. 86182 (June 24, 2019), 84 FR 31128, 31129 (June 28, 2019) (SR–OCC–2019–803).

[29] 12 U.S.C. 5464(b).

[30] 12 U.S.C. 5464(b)(1).

[31] 17 CFR 240.17Ad–22(e)(7).

[32] *Id.*

[33] 17 CFR 240.17Ad–22(e)(7)(i).

[34] *Id.*

implement, maintain and enforce written policies and procedures reasonably designed to hold qualifying liquid resources sufficient to satisfy payment obligations owed to Clearing Members.[35] Rule 17Ad–22(a)(14) of the Exchange Act defines ''qualifying liquid resources'' to include, among other things, lines of credit without material adverse change provisions, that are readily available and convertible into cash.[36] The MRA under the Non-Bank Liquidity Facility would not be subject to any material adverse change provision and would continue to be designed to permit OCC to, among other things, help ensure that OCC has sufficient, readily-available qualifying liquid resources to meet the cash settlement obligations of its largest Clearing Member Group. Therefore, OCC believes that the proposal is consistent with Rule 17Ad–22(e)(7)(ii).[37]

For the foregoing reasons, OCC believes that the proposed changes are consistent with Section 805(b)(1) of the Clearing Supervision Act[38] and Rule 17Ad–22(e)(7)[39] under the Exchange Act.

III. Date of Effectiveness of the Advance Notice and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date the proposed change was filed with the Commission or (ii) the date any additional information requested by the Commission is received. OCC shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

OCC shall post notice on its website of proposed changes that are implemented. The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the advance notice 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–OCC–2022–803 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2022–803. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the advance notice that are filed with the Commission, and all written communications relating to the advance notice 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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–OCC–2022–803 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[40]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15920 Filed 7–25–22; 8:45 am]

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[35] 17 CFR 240.17Ad–22(e)(7)(ii).

[36] 17 CFR 240.17Ad–22(a)(14).

[37] 17 CFR 240.17Ad–22(e)(7)(ii).

[38] 12 U.S.C. 5464(b)(1).

[39] 17 CFR 240.17Ad–22(e)(7).

[40] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95337; File No. SR–NYSE–2022–27]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List Related to Colocation

July 20, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 6, 2022, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN''). The proposed rule change is available on the Exchange's website 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

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 its Price List related to colocation to specify that the NMS feeds that are included in the Included Data Products are no longer available over the Liquidity Center Network (''LCN'').[4]

Background

The LCN and the IP network are the two local area networks in the Mahwah Data Center that are available to Users.[5] General Note 5 of the Price List explains that when a User purchases a service that includes access to the LCN or IP network, it receives connectivity to any of the ''Included Data Products'' that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. The Included Data Products include, among others, the ''NMS feeds,'' which are the Consolidated Tape System and Consolidated Quote System (''CTA'' and ''CQ,'' respectively) data feeds and the Options Price Reporting Authority (''OPRA'') data feed.[6]

Before May 2020, connectivity to the NMS feeds was available on only the LCN and IP networks. In May 2020, the Commission approved the Exchange's proposal to offer Users access to the new ''NMS network,'' an alternate, dedicated network that connects to the NMS feeds faster than the LCN or IP networks.[7] Pursuant to that filing, the Exchange amended the notes regarding the services available in colocation to provide that if a User purchases a service that includes a 10 Gb or 40 Gb LCN or IP network connection, that service would also include a connection to the NMS network of the same size, at no additional charge.

Currently, the NMS feeds are available to Users on all three of the NMS network, IP network, and LCN, but at varying speeds. The NMS feeds are published first to the NMS network, which then republishes them to the IP network, which then republishes them to the LCN. This means that connectivity to the NMS feeds is fastest over the NMS network and slowest over the LCN. This also means that receiving the NMS feeds from more than one of these networks does not provide redundancy protection to Users; if connectivity to the NMS feeds over the NMS network were to be interrupted, so would connectivity to those feeds over the IP network and LCN, since the three networks publish the NMS feeds to each other in sequence.

Despite the Exchange's introduction of the NMS network in May 2020, some Users have failed to avail themselves of the option to receive the NMS feeds over that faster network at no additional cost. Other Users have opted to receive the NMS feeds over the NMS network, but have not yet formally asked the Exchange to stop also sending them the NMS feeds over the other networks (*i.e.,* IP network or LCN) for which those Users have ports.

At the same time, traffic over the LCN has been increasing. Increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements overall for the market data feeds of the Exchange and the Affiliate SROs that are included in the Included Data Products (the ''NYSE Group Market Data'' feeds) over the LCN. As a result, the LCN connections over which some Users continue to receive the NMS feeds are increasingly burdened as the NYSE Group Market Data Feeds continue to grow in size.

To address these issues, the Exchange proposes to remove the NMS feeds from the Included Data Products available on the LCN. Doing so would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN.

To accomplish this change, the Exchange proposes to amend General Note 5 of the Price List as follows (proposed addition italicized):

> 5. When a User purchases a service that includes access to the LCN or IP network it receives connectivity to any of the Included Data Products that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. *Connectivity to the NMS feeds is not available over the LCN, but is available over the IP network and the NMS network described below in General Note 6.* Market data fees for the Included Data Products are charged by the provider of the data feed. A User can change the Included Data Products to which it receives connectivity at any time, subject to authorization from the provider of the data feed. The Exchange is not the exclusive method to connect to the Included Data Products.

Application and Impact of the Proposed Changes

Currently, 34 Users receive the NMS feeds over the LCN, but 23 of those 34 Users have access to the NMS network already enabled, such that they also receive the NMS feeds over the NMS network. To implement this proposal with respect to those 23 Users, the Exchange has notified the Users that their connections to the NMS feeds over LCN will be discontinued but that they will continue to receive the NMS feeds over the NMS network.

The other 11 Users that receive the NMS feeds over the LCN do not currently have NMS network access enabled, but are entitled to such access at no additional charge, since their existing LCN service includes a connection of the same size to the NMS network. The Exchange has notified these 11 Users that their connections to the NMS feeds over LCN will be discontinued, and all 11 of them have submitted orders to begin receiving the NMS feeds over an NMS network connection at no additional charge. The Exchange is currently in the process of installing NMS network connections for those 11 Users.[8]

[4] The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Each of the Exchange's affiliates NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs'') has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSEAMER–2022–28, SR–NYSEArca–2022–39, SR–NYSECHX–2022–15, and SR–NYSENAT–2022–10.

[5] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Price List, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs.

[6] *See* Securities Exchange Act Release No. 79730 (January 4, 2017), 82 FR 3045 (January 10, 2017) (SR–NYSE–2016–92).

[7] *See* Securities Exchange Act Release No. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR–NYSEArca–2019–61, SR–NYSENAT–2019–19). *See also* Securities Exchange Act Release No. 88972 (May 29, 2020), 85 FR 34472 (June 4, 2020) (SR–NYSECHX–2020–18).

[8] Seven of these 11 Users also currently have access to the IP network and could have chosen to receive the NMS feeds over their IP network connections at no additional charge, but instead all

Users would experience no interruption in their ability to connect to the NMS feeds as a result of the proposed change, and would receive the NMS feeds faster as a result of the proposed change. No User would be required to purchase any additional products or services from the Exchange to transition their NMS feed connectivity to the NMS network, or to an IP network connection they have already purchased.

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally. The purchase of any colocation service is completely voluntary and the Price List is applied uniformly to all Users.

No fees are affected by this proposal.

Implementation Date

The Exchange is in the process of transitioning all remaining Users that receive the NMS feeds over the LCN to begin receiving the feeds over NMS network connections at no additional charge. The Exchange expects this transition process to be completed before October 2022. Once that transition is complete, the Exchange proposes to implement this rule change by Customer Notice, at which point the option of receiving the NMS feeds over the LCN would be removed from the Price List.

Competitive Environment

The proposed changes are not otherwise intended to address any other issues relating to colocation services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Users that currently receive the NMS feeds on the LCN would receive the same data at a faster speed via the NMS or IP network, with no interruption of their ability to connect to the NMS feeds. Connectivity to the NMS feeds over the NMS network would be available at no additional charge to affected Users, since their existing LCN service includes a connection of the same size to the NMS network. In addition, connectivity to the NMS feeds over the IP network would be at no additional charge to Users that have already purchased access to the IP network. The Exchange believes that providing connectivity to the same feeds at a faster speed at no additional charge would perfect the mechanisms of a free and open market and a national market system.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would simply give Users that currently receive the NMS feeds on the LCN the opportunity to receive the same data at a faster speed via the NMS network or the IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

The Exchange believes that discontinuing the availability of the NMS feeds on the LCN would not permit unfair discrimination between customers, issuers, brokers, or dealers, because the proposed change would apply equally to all Users that currently receive the NMS feeds over the LCN. Nor does the proposed change advantage Users of the LCN over Users of the IP network, since, as indicated in the Price List, services that include a 10 Gb or 40 Gb LCN or IP connection also include a connection to the NMS network of the same size, at no additional charge.

The Exchange believes that the proposed change would facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because removing the NMS feeds from the LCN would permit Users to receive connectivity to the NYSE Group Market Data feeds over their LCN connections, while the NMS feeds would remain available to Users at no additional charge over the NMS network, at faster speeds than they were available over the LCN. As noted above, increases in options trading volume in recent years on the NYSE American Options and NYSE Arca Options exchanges have increased the size of the market data feeds from those markets, thereby increasing the network bandwidth requirements for the NYSE Group Market Data feeds over the LCN.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed rule change would not place any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues, but rather would provide Users that currently receive the NMS feeds on the LCN the same data at a faster speed via the NMS or IP network, at no additional charge (if they choose to receive the NMS feeds over the NMS network or an already-established IP network connection), with no interruption of their ability to connect to the NMS feeds.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii)

11 have opted to receive the NMS feeds over the faster NMS network.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2022–27 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2022–27. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2022–27 and should be submitted on or before August 16, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–15929 Filed 7–25–22; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17530 and #17531; NORTH DAKOTA Disaster Number ND–00105]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of North Dakota.

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of North Dakota (FEMA–4660–DR), dated 07/13/2022.

Incident: Severe Winter Storm and Flooding.

Incident Period: 04/22/2022 through 05/25/2022.

DATES: Issued on 07/13/2022.

Physical Loan Application Deadline Date: 09/12/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 04/13/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/13/2022, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Adams, Barnes, Billings, Bottineau, Burke, Cavalier, Dickey, Divide, Dunn, Foster, Golden Valley, Grand Forks, Grant, Griggs, Hettinger, Kidder, LaMoure, Logan, McHenry, McIntosh, McKenzie, McLean, Mountrail, Nelson, Oliver, Pembina, Ramsey, Ransom, Renville, Richland, Rolette, Sargent, Steele, Stutsman, Towner, Traill, Walsh, Ward, Wells, Williams.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17530 B and for economic injury is 17531 0.

(Catalog of Federal Domestic Assistance Number 59008)

Joshua Barnes,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–15961 Filed 7–25–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60 Day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act, this notice announces the Small Business Administration's intentions to request approval on a new and/or currently approved information collection.

DATES: Submit comments on or before September 26, 2022.

ADDRESSES: Send all comments regarding whether this information collection is necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collections, to Michael Donadieu, Senior Examiner, 202–255–1007, *michael.donadieu@sba.gov,* Office of Investment, Small Business Administration, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Michael Donadieu, Senior Examiner, 202–255–1007, *michael.donadieu@sba.gov* Curtis B. Rich, Agency Clearance Officer, 202–205–7030 *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: SBA Forms 1405 and 1405A are used by Small Business Administration (SBA) examiners as part of their examination of licensed small business investment companies (SBICs). This information is collected from SBIC'S Stockholders and partners and provides independent third-party confirmation of an SBIC's representations concerning its owners. The information helps SBA to evaluate the SBIC'S with applicable laws and regulations concerning capital requirements.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

PRA Number: 3245–0172

(1) *Title:* ''Stockholders' Confirmation (Corporation); Ownership Confirmation (Partnership)''.

Description of Respondents: Licensed small business investment companies (SBICs).

Form Number: 1405, 1405A.

Total Estimated Annual Responses: 600.

Total Estimated Annual Hour Burden: 600.

Curtis B. Rich,

Agency Clearance Officer.

[FR Doc. 2022–15978 Filed 7–25–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17528 and #17529; MINNESOTA Disaster Number MN–0009]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Minnesota.

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Minnesota (FEMA–4659–DR), dated 07/13/2022.

Incident: Severe Storms, Straight-line Winds, and Flooding.

Incident Period: 04/22/2022 through 06/15/2022.

DATES: Issued on 07/13/2022.

Physical Loan Application Deadline Date: 09/12/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 04/13/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/13/2022, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Beltrami, Clearwater, Cook, Kittson, Koochiching, Lake, Lake Of The Woods, Mahnomen, Marshall, Norman, Pennington, Polk, Red Lake, Roseau, Saint Louis, Bois Forte Band of Chippewa, Leech Lake Band of Ojibwe, Red Lake Nation, and the White Earth Nation.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17528 B and for economic injury is 17529 0.

(Catalog of Federal Domestic Assistance Number 59008)

Joshua Barnes,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–15963 Filed 7–25–22; 8:45 am]

BILLING CODE 8026–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1324X]

Alabama Railroad, LLC—Abandonment Exemption—in Escambia, Conecuh, and Monroe Counties, Ala.

On July 6, 2022, Alabama Railroad, LLC (ARL), filed a petition under 49 U.S.C. 10502 for exemption from the prior approval requirements of 49 U.S.C. 10903 to abandon approximately 47.5 miles of rail line, extending from milepost 607.73 at Flomaton, Ala., to milepost 655.2 near Tunnel Springs, Ala., including all sidings and the MR Junction Spur between valuation stations 0+00 and 90+81 in Escambia, Conecuh, and Monroe Counties, Ala. (the Line). The Line traverses U.S. Postal Service Zip Codes 36426, 36441, 36460, 36471, and 36475.

According to ARL, it purchased the Line from Alabama Railroad Co. (ALAB) in 2020. *See Ala. R.R.—Acquis. & Operation Exemption—Line of Ala. R.R.,* FD 36450 (STB served Nov. 6, 2020). The petition states that prior to ALAB's sale of the Line, ALAB obtained Board authority to abandon the Line but never consummated the abandonment. *See Ala. R.R.—Aban. Exemption—in Escambia, Conecuh, & Monroe Cntys., Ala.,* AB 463 (Sub-No. 2X) (STB served Apr. 18, 2019). ARL states that since it purchased the Line, it has not moved any local traffic over the Line, and, because the Line is stub-ended, there is no overhead traffic. ARL states that it doubts that future demand for service will materialize, particularly at volumes that would warrant restoring operations, and therefore seeks to abandon the Line to facilitate future disposition of the

Line's track assets and underlying right-of-way.

ARL states that, based on the information in its possession, the Line does not contain federally granted rights-of-way and any relevant documentation in ARL's possession related to that statement will be made available promptly to those requesting it.

Citing *Knox & Kane Railroad—Abandonment Exemption—McKean County, Pa.,* AB 551 (Sub-No. 2X) (STB served July 24, 2015), ARL asserts that, because it proposes to abandon its entire railroad system, it is appropriate for the Board to refrain from imposing labor protective conditions because there will be no remaining entity subject to the Board's jurisdiction.

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by October 24, 2022.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 120 days after the filing of the petition for exemption, or 10 days after service of a decision granting the petition for exemption, whichever occurs sooner. Persons interested in submitting an OFA must first file a formal expression of intent to file an offer by August 5, 2022, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(1)(i).

Following abandonment, the Line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for interim trail use/rail banking under 49 CFR 1152.29 will be due no later than August 15, 2022.[1]

All pleadings, referring to Docket No. AB 1324X, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on ARL's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606. Replies to the petition are due on or before August 15, 2022.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment and discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis (OEA) at (202) 245–0294. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

A Draft Environmental Assessment (Draft EA) (or Draft Environmental Impact Statement (Draft EIS), if necessary) prepared by OEA will be served upon all parties of record and upon any other agencies or persons who comment during its preparation. Other interested persons may contact OEA to obtain a copy of the Draft EA (or Draft EIS). Draft EAs in abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the Draft EA generally will be within 30 days of its service.

Board decisions and notices are available at *www.stb.gov.*

Decided: July 21, 2022.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Eden Besera,

Clearance Clerk.

[FR Doc. 2022–15977 Filed 7–25–22; 8:45 am]

BILLING CODE 4915–01–P

[1] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2021–0466]

Agency Information Collection Activities: Requests for Comments; Clearance of a New Approval of Information Collection: Federal Aviation Administration Unmanned Aircraft Systems Support Center Case Management System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for a new information collection. The Federal Aviation Administration (FAA) Unmanned Aircraft Systems (UAS) Support Center Case Management System (CMS) is being created to help streamline how stakeholders' questions are answered in a timely manner. Specifically, the Contact Customer Support form allows the public and other stakeholders to ask the FAA questions, as well as get the appropriate answer or information they need to operate their UAS or drone safely. The UAS Support Center has a publicly available form to submit inquiries. This form would be replacing the current web form to be used within the Salesforce solutions that allows UAS Integration Office additional technology to more efficient and streamline the UAS Support center business process. This form would allow the UAS Integration Office to collect the appropriate information about the stakeholder's name, preferred method of communications email address, phone number, zip code, type of flyer that would allow the Support Center Analysts to answer the customer's specific question more efficiently.

DATES: Written comments should be submitted by August 25, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Mark Hyatt, 490 L'Enfant Plaza, Suite 2206, Washington, DC 20024.

By fax: 202–267–8249.

FOR FURTHER INFORMATION CONTACT: Mark Hyatt by email at: *mark.hyatt@faa.gov;* phone: 202–267–3676.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized 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.

OMB Control Number: 2120–XXXX.

Title: Federal Aviation Administration (FAA) Unmanned Aircraft Systems (UAS) Support Center Case Management System (CMS).

Form Numbers: Customer Inquiry form; Customer Inquiry Status Check Form.

Type of Review: New Information Collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 7, 2021 (Document Citation: 86 FR 30368).

The Federal Aviation Administration (FAA) Unmanned Aircraft Systems

(UAS) Support Center Case Management System (CMS) will streamline how respondents' questions will be answered. Specifically, the UAS Support Center CMS Customer Inquiry form allows the public and other stakeholders to ask the FAA questions, as well as get the appropriate answer/information that is needed to operate their UAS or drone safely.

The UAS Support Center will have a publicly available form to submit inquiries. This form will allow the UAS Support Center to collect the appropriate information about the respondent's name (*i.e.,* first and last), preferred method of communications (*i.e.,* email or phone), email address, phone number, zip code (if needed), self-identification of type of flyer (*i.e.,* recreational, commercial/business, public safety, local government, educational/research, Eyewitness Report, I don't know, and other), the subject of the inquiry, and inquiry/question). This information will allow the UAS Support Center Analysts more information to efficiently answer the respondent's specific question.

The respondents public form process starts with submitting an inquiry by using the public webform, shared email inbox, or by calling the UAS Support Center Analysts. Once the public user submits an inquiry, they will receive an automated system email receipt that includes inquiry reference number, created date, ''tell us about yourself,'' subject, and their inquiry/question. The public users can also use the inquiry status public page to check their inquiry status. For a public user to check the status of an inquiry, the system requires the user to have and enter the reference number and email address that is used to when creating the inquiry. Once the system confirms that the email address and reference number match with the inquiry record that's currently in the system, it will display inquiry status and created date of the inquiry.

The FAA received comments to the 60-day **Federal Register** Notice from the Small UAV Coalition, MAC Law, and one individual.

- The FAA considered all comments equally.
- The FAA agrees with the request for the system to send a confirmation email with the confirmation tracking code to track the status of the inquiry, similar to the *www.regulations.gov* website. This functionality is built into the system and will not allow for members of the public to view the status of another stakeholder's inquiry.
- The Case Management System collects appropriate information about the stakeholder's name, preferred method of communication, phone number, zip code, and type of flyer to facilitate quick resolution of stakeholder inquiries. It will provide a historical record of an individual's inquiries for the UAS Support Center to reference.
- The FAA references the support center on *FAA.gov/uas,* UAS events, community partnerships and social media.
- The FAA provides the opportunity for a stakeholder to contact the FAA UAS Support Center by phone and/or email.The FAA commits to protecting personally identifiable information (PII) in response to a Freedom of Information Act request, under 5 U.S.C. 552(b)(6). In response, a text-based warning to avoid including PII will be included on the inquiry page to prevent unnecessary collection of this information.

Respondents: Anyone may use the publicly available form to submit an inquiry. The respondent may submit any number of inquiries.

Frequency: N/A.

Estimated Average Burden per Response: Less than two minutes for a typical inquiry.

Estimated Total Annual Burden: The majority of respondents submit a one-time inquiry. The annual burden per respondent per inquiry is two minutes. Estimate around 22,000 inquiries per year equating to 44,000 minutes of total burden to the public per year.

Issued in Washington, DC.

Danielle Corbett,

Manager, UAS Integration Office, Program and Data Management, AUS–410.

[FR Doc. 2022–15894 Filed 7–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Buy America Waiver Notification

AGENCY: Maritime Administration, U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice provides information regarding the finding of the Maritime Administration (MARAD), in coordination with the Federal Highway Administration (FHWA), that it is appropriate to grant a Buy America waiver based on nonavailability to the Philadelphia Regional Port Authority (PhilaPort) for procurement of foreign iron and steel components for the Packer Avenue Marine Terminal (PAMT) Capacity and Warehouse Relocation FY2017–2018 Infrastructure for Rebuilding America (INFRA) project. The foreign iron and steel components are part of a Medium Voltage (MV) Cable Reel System, which is necessary for the conversion of two ship-to-shore (STS) cranes' drive power supply from diesel to electric. The non-domestic parts include: (i) Drive Gearbox and Motors; (ii) Electrical and Communications Collector System; (iii) MV cable drum; (iv) MV cable guides and diverter mounted to STS structure/legs; and (v) Gantry level bi-directional multi-roller, curved cable guide.

DATES: The effective date of the waiver is July 27, 2022.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Robert Bouchard, Director, Office of Port Infrastructure Development, 202–366–5076 or via email at *Robert.Bouchard@dot.gov.* For legal questions, please contact Lauren Gill, MARAD Office of Chief Counsel, 202–366–2150, or via email at *Lauren.Gill@dot.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at: *www.FederalRegister.gov* and the Government Publishing Office's database at: *www.GovInfo.gov.*

Background

PhilaPort's FY2017–2018 INFRA Project is required to follow the FHWA's Buy America requirements at 23 U.S.C. 313 and implementing regulations at 23 CFR 635.410. FHWA's Buy America regulation in 23 CFR 635.410 requires a domestic manufacturing process for any steel or iron products (including protective coatings) that are permanently incorporated in a Federal-aid construction project. The regulation also provides for a waiver of the Buy America requirements when the application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not produced in the United States in sufficient and reasonably available quantities. This notice provides information regarding MARAD's finding that it is appropriate to grant the PhilaPort a Buy America waiver based on nonavailability for procurement of foreign iron and steel components for the MV Cable Reel System, which is necessary for the conversion of two ship-to-shore (STS) cranes' drive power supply from diesel to electric. The non-domestic parts include: (i) Drive Gearbox and Motors; (ii) Electrical and Communications Collector System; (iii) MV cable drum; (iv) MV cable guides and diverter mounted to STS structure/

legs; and (v) Gantry level bi-directional multi-roller, curved cable guide.

Background on the Project: The DOT awarded PhilaPort [1] a $25.5M FY2017–2018 INFRA grant [2] for its PAMT Capacity and Warehouse Relocation Project, which has a total project cost of roughly $122M.[3] MARAD is designated as the DOT operating agency responsible for administering the Project. The Project includes the electrification of two existing Hyundai STS diesel cranes (referred to as H–6 and H–7) to eliminate air emissions and improve operational reliability. The cranes were installed at PAMT in 2004 and are the most utilized cranes on the terminal for unloading cargo from container vessels. According to PhilaPort, depending on the workload, the cranes can consume between 20 to 100 gallons of diesel fuel per hour.

PhilaPort determined that delivering utility-supplied electric power to the STS cranes required a trailing MV Cable Reel System. The MV Cable Reel System allows the STS cranes to be mobile along the dock by reeling cable in and out from a motorized and synchronized cable drum as the crane moves along the berth. The cable also delivers fiber communications to and from the cranes and the terminal. PhilaPort currently has five other STS cranes that operate alongside the H–6 and H–7 cranes that use a similar MV Cable Reel system. Additionally, the dock where H–6 and H–7 operate has been retrofitted to allow for the electrification of the two cranes via this system.

The crane electrification project will have substantial environmental benefits due to the elimination of harmful air emissions after the transition to electric drives. PhilaPort's PAMT has a planned annual container throughput that is forecasted to require 4,103 hours of operation for both H–6 and H–7. At this level of operation, PhilaPort estimates that converting the cranes to utility-supplied electricity would eliminate 109,896 of diesel crane hours and over 100,000 tons of harmful air emissions over their lifetime. Additionally, the conversion of the cranes from diesel to electric will result in significant cost savings to PhilaPort due to the reduction in fuel usage, energy costs, and improvements in efficiency and reliability of the cranes.

Background on the Waiver Request: PhilaPort began designing the crane electrification project in April 2020, at which point it became apparent that a Buy America-compliant MV Cable Reel System could not be sourced domestically. After further discussions with MARAD, PhilaPort requested that the design engineer perform a market study among potential suppliers. The design engineer contacted three known suppliers in the industry and one potential supplier in a related industry. All four respondents confirmed that they could not supply a fully Buy America-compliant MV Cable Reel System.

After receiving the results of the market study and discussing with MARAD, PhilaPort proceeded to bid the crane electrification project in the hope that bidding contractors could engage resources to identify a fully Buy America-compliant MV Cable Reel System. On June 28, 2021, PhilaPort received bids on the Project from only two contractors, both of whom proposed the same non-compliant supplier for the MV Cable Reel System.

After unsuccessfully identifying domestic manufacturers of the MV Cable Reel System, on September 8, 2021, PhilaPort submitted a Buy America waiver request to MARAD for the procurement of an MV Cable Reel System containing foreign iron and steel components needed to complete the PAMT INFRA Project. The foreign components [4] include: (i) Drive Gearbox and Motors; (ii) Electrical and Communications Collector System; (iii) MV cable drum; (iv) MV cable guides and diverter mounted to STS structure/legs; and (v) Gantry level bi-directional multi-roller, curved cable guide.

The MV Cable Reel System is included under an approximately $5.5 million contract to complete the crane electrification project. PhilaPort estimates that the MV Cable Reel System itself will cost $410,000 out of that total project cost. Of the $410,000, approximately $110,000, or 2% of the total contract cost, is the cost of the foreign steel and iron components contained in the MV Cable Reel System. The remaining $300,000 is non-steel/iron electrical trailing cable. All other costs associated with this contract are expected to comply with Buy America requirements.

In accordance with the statutory requirement at 23 U.S.C. 313(g), MARAD published a notice of intent to issue a waiver on the FHWA website on April 27, 2022, at *https://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=165.* MARAD received no comments in response to the publication. Additionally, the PhilaPort point of contact similarly did not receive any comments or inquiries. Thus, PhilaPort did not receive any new information indicating that the subject components could be produced by domestic manufacturers.

Although PhilaPort did not identify a Buy America-compliant MV Cable Reel System, it provided information to MARAD supporting its waiver request, including information:

- Supporting the necessity of the MV Cable Reel System for converting the STS cranes from diesel to electric;
- Documenting efforts to locate compliant manufactured products;
- Demonstrating that alternative designs were infeasible; and
- Describing the effects of denying the request.

Although ultimately unsuccessful, PhilaPort made substantial efforts to find a Buy America-compliant MV Cable Reel System.

Timing and Need for a Waiver. According to PhilaPort, the approval of a Buy America waiver for the MV Cable Reel System is critical to maintain the schedule of ongoing construction on the INFRA Project. Currently, the lead time for this major component is between 20 to 30 weeks, so any delay in approving the waiver will result in project delays and additional time the STS cranes will operate under diesel power. Without the waiver for the relevant system, the crane electrification project cannot move forward, and the environmental and operational benefits of the project would be lost.

Executive Order 14005. Executive Order 14005, ''Ensuring the Future is Made in All of America by All of America's Workers,'' provides that agencies should, consistent with applicable law, maximize the use of goods, products, and materials produced in, and services offered in, the U.S. 86 FR 7475 (Jan. 28, 2021). Based on the information contained in the waiver request from PhilaPort and the lack of comments following publication of a notice seeking comment on April 27, 2022, regarding available domestic manufacturers for the subject parts, MARAD concludes that issuing a waiver is consistent with Executive Order 14005.

Finding and Request for Comments

Based on all the information available to the Agency, MARAD concludes that there are no Buy America-compliant

[1] PhilaPort's Unique Entity Identifier (UEI) is J4QYLRK4VSR5.

[2] The INFRA program is described under the assistance listing program title ''Nationally Significant Freight and Highway Projects'' (assistance listing number 20.934).

[3] The Federal Award Identification Number (FAIN) for the INFRA project is 693JF71910026.

[4] Depending on which vendor is selected by PhilaPort, the country of origin for these components will most likely be either Germany or Italy.

relevant components for the MV Cable Reel System needed for the Project, including: (i) Drive Gearbox and Motors; (ii) Electrical and Communications Collector System; (iii) MV cable drum; (iv) MV cable guides and diverter mounted to STS structure/legs; and (v) Gantry level bi-directional multi-roller, curved cable guide. This finding only includes components identified in the waiver request and supporting documents included on FHWA's website.

The PhilaPort and its contractors and subcontractors involved in the procurement of the relevant components are reminded of the need to comply with the Cargo Preference Act in 46 CFR part 381, if applicable.

To avoid the possibility of requiring waivers for these items in the future, MARAD will work with industry to better understand the demand for these components and the potential for domestic production of these items in the future. We will then follow-up with the Office of Management and Budget's Made in America Office and the U.S. Department of Commerce, as appropriate, to assess the potential for domestic production to meet the forecasted demand for these items.

In accordance with the provisions of Section 117 of the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244, 122 Stat. 1572), MARAD is providing this notice as its finding that a waiver of Buy America requirements is appropriate. MARAD invites public comment on this finding for an additional 5 days following the effective date of the finding. Comments may be submitted to FHWA's website via the link provided to the waiver page noted above.

(Authority: 23 U.S.C. 117; 23 U.S.C. 313; Pub. L. 110–244; 23 CFR 635.410)

By order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–16012 Filed 7–25–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0043]

Agency Information Collection Activities; Notice and Request for Comment; Consolidated Labeling Requirements for Motor Vehicles (Except the VIN)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for extension of a currently-approved information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. Before a Federal agency can collect certain information from the public, it must receive approval from 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 reinstatement of previously approved collections. *This document describes a collection of labeling information on seven Federal Motor Vehicle Safety Standards (FMVSS) for which NHTSA intends to seek OMB approval. The labeling requirements include brake fluid warning, glazing labeling, air bag warning labels, seat belt labeling, compressed natural gas (CNG) vehicle fuel label, and CNG fuel container labels.*

DATES: Comments must be submitted on or before September 26, 2022.

ADDRESSES: You may submit comments, identified by the NHTSA docket number identified above, through any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this proposed collection of information. 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.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact James Myers, NHTSA, 1200 New Jersey Avenue SE, West Building, Room W43–320, NRM–100, Washington, DC 20590. Mr. Myers' telephone number is 202–366–1810. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first 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 regulation (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;

(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 for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: Consolidated Labeling Requirements for Motor Vehicles (except the VIN).

OMB Control Number: 2127–0512.

Type of Request: Extension of a currently approved collection.

Type of Review Requested: Regular.

Summary of the Collection of Information: 49 U.S.C. 30111 authorizes the issuance of Federal motor vehicle safety standards (FMVSS). The agency, in prescribing a FMVSS, considers available relevant motor vehicle safety data, and consults with other agencies, as it deems appropriate. Further, the statute mandates that in issuing any FMVSS, the agency considers whether the standard is ''reasonable, practicable and appropriate for the particular type of motor vehicle or item of motor vehicle equipment for which it is prescribed,'' and whether such a standard will contribute to carrying out the purpose of the Act.

The Secretary is authorized to invoke such rules, as deemed necessary to carry out these requirements. Using this authority, the agency issued the following FMVSS, specifying labeling requirements to aid the agency in achieving many of its safety goals:

FMVSS No. 105, ''Hydraulic and electric brake systems,''

FMVSS No. 135, ''Light vehicle brake systems,''

FMVSS No. 205, ''Glazing materials,''

FMVSS No. 208, ''Occupant crash protection,''

FMVSS No. 209, ''Seat belt assemblies,''

FMVSS No. 303, ''Fuel system integrity of compressed natural gas vehicles,'' and

FMVSS No. 304, ''Compressed natural gas fuel container integrity.''

This notice requests comments on the labeling requirements of these FMVSS.

FMVSS No. 105 and FMVSS No. 135 require that each vehicle shall have a brake fluid warning statement in letters at least one-eighth of an inch high on the master cylinder reservoirs. The lettering shall be permanently affixed, engraved, or embossed and located so as to be visible by direct view. If not engraved or embossed, it should be a color that contrasts with its background.

Vehicle manufacturers provide warning statements on hydraulic brake reservoirs for an estimated 1,003 vehicle models.[1] Although the required statements have been in use for many years, there is an annual 1 hour burden for manufacturers to have a Mechanical Drafter[2] reverify that their statements still meet the regulatory requirements. The annual burden for this reverification is 1,003 hours (1,003 vehicle model lines * 1 hour per model line) and $40,476 (1,003 vehicle models * 1 hour per label * $28.37 labor rate per hour ÷ 70.3% of labor rate as total wage compensation). Manufacturers will also bear a cost burden of $296,372 (17,961,961 brake reservoir caps/plugs * 1.1 spare parts factor * $0.015 per part) for the required labeling text to be applied to the hydraulic reservoir plugs and caps. The combined total annual burden for vehicle manufacturers to have the specified text on the hydraulic reservoir plugs and caps is 1,003 hours and $296,372. This is an increase in the cost burden of 265,328 due to adjustments in annual vehicles produced and addition of the per part expenses.

FMVSS No. 205, provides labeling requirements for glazing and motor vehicle manufacturers. In accordance with the standard, each new motor vehicle glazing manufacturer must request a unique identifying number. This number is used in their self-certification label, which also identifies the glazing type, and is permanently attached to each piece of motor vehicle glazing. Certain specialty glazing items, such as standee windows in buses, roof openings, and interior partitions made of plastic require that the manufacturer affix an additional, removable label to each item. This removable label specifies cleaning instructions to minimize the loss of transparency. Other information may be provided by the manufacturer.

Glazing manufacturers are required to have a DOT manufacturer's code mark for each of their glazing production facilities. This code mark is part of the manufacturer's certification label applied to glazing covered by FMVSS No. 205. An average of 22 glazing manufacturers annually complete an online request for a new DOT manufacturer's code mark. New code mark applications take an hour for a Project Management or Business Operations Specialist,[3] to complete. This places an annual burden on applicants of 22 hours (22 manufacturers * 1 hour per manufacturer) and $1,268 (22 hours * $40.53 per hour wage ÷ 70.3% of labor rate as total wage compensation) to obtain new DOT manufacturer's code marks. In addition, it is estimated a Mechanical Drafter[4] will require 40.0 hours to develop a certification label template for a new code mark, for an annual burden of 880 hours (22 manufacturers * 40.0 hours per manufacturer) and $35,513 (22 manufacturers * 40 hours per manufacturer * $28.37 per hour wage ÷ 70.3% of labor rate as total wage compensation). All glazing manufacturers will annually require 2.0 hours for a Mechanical Drafter to insert and verify correct information for each certification label for the estimated 9,452[5] glazing model lines produced annually, for a burden of 18,904 hours (2.0 hours per glazing certification label * 9,452 glazing model needing certification label) and $762,883 (9,452 glazing model labels * 2.0 hours per glazing model label * $28.37 per hour wage ÷ 70.3% of labor rate as total wage compensation). Two different labeling methods are used by the industry, ceramic paint (90% of market) and sand blasting (10% of market). Annually, vehicle manufacturers bear a cost burden of $2,825,732 ([142,713,747 vehicle glazing panels[6] * 1.1 spare parts

[1] 1,003 vehicle model lines equals 645 heavy vehicle models with a GVWR of 3,500 kilograms (7,716 pounds) or less and 358 light vehicle models with a GVWR greater than 3,500 kilograms (7,716 pounds).

[2] The Bureau of Labor Statistics (BLS) estimates the mean hourly wage for a Mechanical Drafter, occupational code 17–3013, to be $28.37. Further, the BLS estimates the hourly wage to represent only 70.3% of the total compensation for workers.

[3] The Bureau of Labor Statistics (BLS) estimates the mean hourly wage for a Project Management or Business Operations Specialists, occupational code 13–1198, to be $40.53. Further, the BLS estimates the hourly wage to represent only 70.7% of the total compensation for workers.

[4] The Bureau of Labor Statistics (BLS) estimates the mean hourly wage for a Mechanical Drafter, occupational code 17–3013, to be $28.37. Further, the BLS estimates the hourly wage to represent only 70.3% of the total compensation for workers.

[5] It is estimated that there are 174 passenger vehicle models (per 2020 Wards Intelligence data) requiring 8 glazing model numbers, 184 light truck models requiring 15 glazing model numbers, 51 medium/heavy truck models requiring 9 glazing model numbers, 156 light and medium bus models requiring 8 glazing models, 284 motorcycle models requiring 1 glazing model, 108 slide-in camper models requiring 2 glazing model numbers, 438 camper models requiring 7 glazing model numbers, and 9 pick-up bed covers requiring 3 glazing models. The total estimated number of glazing model numbers is 9,452 [(174 * 8) + (184 * 15) + (51 * 9) + (156 * 8) + (284 * 1) + (108 * 2) + (438 * 7) + (9 * 3)].

[6] It is estimated that there are 4,715,005 passenger cars each with 8 glazing units, 12,237,907 light truck vehicles each with 15 glazing units, 527,092 medium/heavy truck vehicles each with 9 glazing units, 17,200 medium and heavy bus vehicles each with 8 glazing units, 472,000 motorcycles each with 1 glazing unit, 11,000 slide-in campers each with 2 glazing units, 464,757 campers each with 7 glazing units, and 8,000 pick-up bed covers each with 4 glazing units. The total estimated number of

factor * $0.015 per part * 90%] + [142,713,747 vehicle glazing panels * 1.1 spare parts factor * $0.045 per part * 10%]) to apply the required certification label to glazing panels.

Certain types of glazing material, generally used in standee partitions of transit buses, require a cleaning label. Although the required statements have been in use for many years, there is an annual 1 hour burden for manufacturers to have a Mechanical Drafter reverify their statements still meet the regulatory requirements. This adds a burden of 36 hours and $1,453 (36 glazing cleaning labels [7] [8] * 1.0 hours per cleaning label * $28.37 per hour wage ÷ 70.3% of labor rate as total wage compensation). Application of cleaning labels to the those glazing panels adds a cost burden of $12,770 (1 label per applicable glazing panel * 2 applicable panels per bus * 5,300 transit buses [9] * $0.73 per label cost). The total annual burden due to labeling requirements of FMVSS No. 205 is 19,842 hours and $3,639,619.

FMVSS No. 208, specifies requirements for both active and passive occupant crash protection systems for passenger cars, multipurpose passenger vehicles, trucks, and small buses. A label is to be affixed to either side of the sun visor at each front outboard seating position that is equipped with an inflatable restraint. The label warns of dangers a deploying air bag poses to children 12 and under. Each vehicle that is equipped with an inflatable restraint for the passenger position shall have a label attached to a location on the dashboard or steering wheel hub that is clearly visible from all front seating positions. These labels advise occupants to always use seat belts, the back seat is the safest place for children, and to never place a rear-facing child seat in the front. Additionally, if a vehicle manufacturer recommends periodic maintenance or replacement of an inflatable restraint system installed in a vehicle, that vehicle must be labeled with the recommended schedule for maintenance or replacement.

It is estimated that vehicle manufacturers provide air bag warning labels for 565 vehicle models. Text and graphics for the warning labels are supplied in the Regulatory text, and these labels have been in use for many years. A Mechanical Drafter [10] performs the 1 hour of annual work per vehicle model necessary to confirm the label design prior to it being printed onto sun visors. The annual burden to manufacturers for the warning label reviews is 565 hours (565 vehicle model lines * 1 hour per model line) and $11,268 (565 vehicle models [11] * 1 hour per label * $28.35 labor rate per hour ÷ 70.3% of labor rate as total wage compensation). Annually, vehicle manufacturers bear a cost burden of $8,772,284 (34,977,208 sun visors [12] * 1.1 spare parts factor * $0.228 per part cost for label application) to apply the required warning labels to sun visors.

Vehicle manufacturers provide an estimated 565 vehicle models with dashboard warning labels. Text and graphics for the dashboard labels are supplied in the Regulatory text, and these labels have been in use for many years. A Mechanical Drafter performs the 1 hour of annual work per vehicle model necessary to confirm the dashboard label design. The annual burden to manufacturers for the dashboard label reviews is 565 hours (565 vehicle model lines * 1 hour per model line) and $11,268 (565 vehicle models [13] * 1 hour per label * $28.35 labor rate per hour ÷ 70.3% of labor rate as total wage compensation). Annually, vehicle manufacturers bear a cost burden of $9,897,386 (17,497,204 vehicle dashboards [14] * 1.1 spare parts factor * $0.472 per dashboard warning label) to have the required warning labels on dashboards.

No vehicle manufacturers are currently using air bags that require replacement or periodic maintenance. Since no manufacturers equip vehicles with air bags requiring maintenance or replacement, there is no annual administrative burden to include such information on any vehicle label.

The combined total annual burden to vehicle manufacturers from the dashboard and sun visor warning labels is 1,130 hours and $17,879,368. These hour and cost burdens represent a new addition to this information collection request.

FMVSS No. 209 requires safety belts to be labeled with the year of manufacture, the model, and the name or trademark of the manufacturer.[15] Additionally, seat belt assemblies for use only in specifically stated motor vehicles, other than a seat belt assembly installed in a motor vehicle by an automobile manufacturer, shall either be permanently and legibly marked or labeled with the following statement, or the statement shall be in the instruction sheet required for seat belt assemblies not installed in a motor vehicle by an automotive manufacturer:

This seat belt assembly is for use only in [insert specific seating position(s), *e.g.,* ''front right''] in [insert specific vehicle make(s) and model(s)].[16]

It is estimated manufacturers choose to include this statement in installation instruction sheets required for spare parts as a more cost-efficient method compared to labeling all seat belt assemblies for a particular vehicle model.

It is estimated that vehicle manufacturers provide labels on 4,139 [17] different seat belt assembly models. Manufacturers have provided seat belt assemblies with the required labels for many years. It is estimated each manufacturer has a generalized label template which only requires population with the correct model number and manufacturing date. There is an annual 2.0 hour burden for manufacturers to have a Mechanical Drafter put the correct information into a label template to create a model specific label. The annual burden for this label creation is 8,278 hours (4,139 seat belt models * 2 hour per model label) and $334,064 (4,139 seat belt

glazing model numbers is 142,713,747 [(4,715,005 * 8) + (12,237,907 * 8) + (527,092 * 6) + (17,200 * 8) + (472,000 * 1) + (11,000 * 3) + (464,757 * 7) + (8,000 * 4)].

[7] There are 36 manufacturers producing transit buses. Source: David Czerwinski et al., *The US Transit Bus Manufacturing Industry* (Mineta Transportation Institute, 2016), 10.

[8] Each manufacturer can use a common cleaning label for all of their vehicle models.

[9] David Czerwinski et al., *The US Transit Bus Manufacturing Industry* (Mineta Transportation Institute, 2016), 10.

[10] The Bureau of Labor Statistics (BLS) estimates the mean hourly wage for a Mechanical Drafter, occupational code 17–3013, to be $29.09. Further, the BLS estimates the hourly wage to represent only 70% of the total compensation for workers.

[11] NHTSA estimates there are 565 vehicle models requiring sun visor labels annually (174 passenger car, 185 light truck, 51 medium/heavy truck, and 156 large/medium bus models). Vehicle model data from 2020 Wards Intelligence data.

[12] NHTSA estimates there are a total of 38,474,929 sun visors with warning labels produced annually. This total includes 2 warning labels in the 4,715,005 passenger cars: 12,237,907 light truck vehicles, and 527,092 medium and heavy trucks. There is a sun visor with an air bag warning label in each of the 17,200 medium and heavy buses [2* (4,715,005 + 12,237,907 + 527,092) + 1 * (17,200)].

[13] NHTSA estimates there are 565 vehicle models requiring sun visor labels annually (174 passenger car, 185 light truck, 51 medium/heavy truck, and 156 large/medium bus models). Vehicle model data from 2020 Wards Intelligence data.

[14] Only one dashboard warning per vehicle is required. The number of dashboard labels is half the number of sun visor labels. NHTSA estimates there are 14,497,204 dashboard warning labels produced annually.

[15] FMVSS No. 209, S4.1(j).

[16] FMVSS No. 209, S4.1(k).

[17] For the estimated 174 passenger car, 184 light truck, 51 medium/heavy truck, 156 medium/heavy bus, and 438 camper models there are an estimated average of 5, 7, 5, 3, and 2 unique seat belt assemblies, respectively, per vehicle type. Additionally, it is estimated there are approximately 376 non-OEM aftermarket seat belt assembly models sold annually. Each seat belt assembly has 1 label per seat belt assembly model. This equates to a total of 4,376 unique seat belt assembly model labels.

models * 2 hour per model label * $28.37 labor rate per hour ÷ 70.3% of labor rate as total wage compensation). Manufacturers will also bear a cost burden of $4,287,219 (112,970,199 [18] seat belt assemblies * 1.1 spare parts factor * $0.035 per label) for the required labels to be attached to the seat belt assemblies.

The combined total annual burden to vehicle manufacturers from the requirements to have the specified label text on seat belt assemblies is 8,278 hours and $4,621,283. This is an increase in the cost burden of $4,558,103 due to the adjustments in the number of vehicles produced annually and accounting for the per part expense.

FMVSS NO. 303 specifies requirements for the integrity of motor vehicle fuel systems using compressed natural gas (CNG), including the CNG fuel systems of bi-fuel, dedicated, and dual fuel CNG vehicles. Each CNG must have a permanent label which lists the CNG service pressure and a statement directing vehicle users/operators to instructions for inspection and service life of the fuel container.

It is estimated that vehicle manufacturers provide labels on 18 different CNG vehicle models. Manufacturers have provided CNG vehicles with the required labels for many years, it is estimated each manufacturer has a generalized label template which only requires population with the correct model number and manufacturing date. There is an annual 1.0 hour burden for manufacturers to have a Mechanical Drafter put the correct information into a label template to create a model specific label. The annual burden for this label creation is 18 hours (18 CNG vehicle model labels * 1 hour per model label) and $726 (18 CNG vehicle model labels * 1 hour per model label * $28.37 labor rate per hour ÷ 703% of labor rate as total wage compensation). Manufacturers will also bear a cost burden of $3.651 (5,000 CNG vehicles * $0.73 per label) for the required labels to be attached to the CNG vehicles. The combined total annual burden to vehicle manufacturers from the requirements to have the specified label text on CNG vehicles is 18 hours and $4,377. These hour and cost burdens represent a new addition to this information collection request.

FMVSS No. 304 specifies requirements for the integrity of compressed natural gas (CNG), motor vehicle fuel containers. Each CNG fuel container must have a permanent label containing information relating to the proper use, installation, and maintenance of the CNG container.

It is estimated that manufacturers provide labels on 100 different CNG container models. Manufacturers have provided CNG containers with the required labels for many years. It is estimated each manufacturer has a generalized label template which only requires population with the correct model number and manufacturing date. There is an annual 1.0 hour burden for manufacturers to have a Mechanical Drafter put the correct information into a label template to create a model specific label. The annual burden for this label creation is 100 hours (100 CNG container model labels * 1.0 hours per model label) and $4,036 (100 CNG container models labels * 1.0 hours per model label * $28.37 labor rate per hour ÷ 70.3% of labor rate as total wage compensation). Manufacturers will also bear a cost burden of $14,603 (20,000 CNG containers * $0.730 per label) for the required labels to be attached to the CNG vehicles. The combined total annual burden to vehicle manufacturers from the requirements to have the specified label text on CNG containers is 100 hours and $18,639. These hour and cost burdens represent a new addition to this information collection request.

Description of the Need for the Information and Proposed Use of the Information: All labeling included in this collection is placed on motor vehicle equipment at the time it is manufactured. All safety labeling requirements are necessary for vehicle use on the nation's highways. The lack of labeling could allow improper items of motor vehicle equipment to be installed on motor vehicles and could be the subject of failures or inadequate injury mitigations—increasing the risk for vehicle crashes, severe injuries, and even deaths. Lack of airbag warning labels could encourage placement of children in the front passenger seating position, where the child would be less safe in an accident than if placed in a back-row seating position. The lack of CNG container labeling could result in improper use of CNG containers resulting in a fire or explosion.

As for the identification of glazing manufacturers, the collection of information is only required one time. Absence of this DOT code mark would mean the glazing material would be available to the public without manufacturer's proof that the material passed minimum safety standards. Additionally, if the information were not collected, the ability to determine the identification of the glazing manufacturer in crashes involving defects would be placed in jeopardy.

Affected Public: Vehicle manufacturers.

Estimated Number of Respondents: 22.

Frequency: On occasion.

Number of Responses: NHTSA anticipates that approximately 22 new prime glazing manufacturers per year will contact the agency and request a manufacturer identification number. These new glazing manufacturers must submit one application, one time, identifying their company. In turn, the agency responds by assigning them a unique manufacturer number. For other collections in this notice, no response is necessary from manufacturers. These labels are only required to be placed on each master cylinder reservoir, glazing pane, sun visor, and each safety belt intended for retail sale in the United Sates. Therefore, the number of respondents is limited to the glazing manufacturers requesting a manufacturer identification number.

Estimated Total Annual Burden Hours: 30,371.

Estimated Total Annual Burden Cost: $26,334,780.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2022–16021 Filed 7–25–22; 8:45 am]

BILLING CODE 4910–59–P

[18] It is estimated that there are 4,715,005 passenger cars each with 5 unique seat belt assemblies; 12,237,907 light truck vehicles each with 7 unique seat belt assemblies; 527,092 medium/heavy truck vehicles each with 6 glazing units, 17,200 medium and heavy bus vehicles each with 3 unique seat belt assemblies; and 464,757 campers each with 2 unique seat belt assemblies. Additionally, it is estimated that 50,000 non-OEM aftermarket seat belt assemblies are produced each yeat. The total estimated number of seat belt assemblies is 112,920,199 [(4,715,005 * 5) + (12,237,907 * 7) + (527,092 * 5) + (17,200 * 3) + (464,757 * 2) + (50,000)].

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket Number NHTSA–2022–0046]

Agency Information Collection Activities; Notice and Request for Comment; Replaceable Light Source Dimensional Information Collection

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for public comments on a request for reinstatement of a previously approved information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a reinstatement of a previously approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from 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 a collection of information for which NHTSA intends to seek OMB approval on replaceable light source dimensional information.

DATES: Comments must be received on or before September 26, 2022.

ADDRESSES: You may submit comments identified by docket number NHTSA–20##–#### through any of the following methods:

- *Electronic Submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.

Instructions: All submissions must include the agency name and docket number. 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 discussion below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read comments received, go to *http://www.regulations.gov* at any time or to the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Evan Frings, U.S. Department of Transportation, National Highway Traffic Safety Administration, West Building W43–462, 1200 New Jersey Avenue SE, Washington, DC 20590. (202) 366–7021. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), 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 submissions of responses. In compliance with these requirements, NHTSA asks for public comment on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: 49 CFR Part 564, Replaceable Light Source Dimensional Information Collection.

OMB Control Number: 2127–0563.

Type of Request: Reinstatement of a previously approved collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: Pursuant to 49 CFR part 564, ''Replaceable Light Source and Sealed Beam Headlamp Information,'' manufacturers of newly designed or modified replaceable headlamp light sources are required to submit interchangeability and performance specifications to NHTSA not later than 60 days before beginning manufacture of a replaceable light source product. The specific dimensional, electrical specification, and marking/designation information that must be submitted is specified in Appendices A and B of part 564. After a short agency review to assure completeness, the information is placed in a public docket for use by any person who would like to manufacture headlamp light sources for motor vehicles. In Federal motor vehicle safety standard (FMVSS) No. 108, ''Lamps, reflective devices and associated equipment,'' information submitted in accordance with Part 564 is referenced as the source for the performance and interchangeability information for legal headlamp light sources, whether original equipment or replacement equipment. The submitted information about headlamp light sources becomes the basis for certification of compliance with safety standards.

Description of the Need for the Information and Proposed Use of the Information: The purpose of this information collection is to ensure the availability to replacement light source manufacturers of the manufacturing specifications of original equipment lights sources so that replacement light sources are interchangeable with original equipment light sources and provide equivalent performance, and to ensure that redesigned or newly developed light sources are designated as distinct, different, and noninterchangeable with previously existing lights sources.

The information collected is to be placed in a public docket for use by vehicle, headlamp and headlamp light source manufacturers for determining the interchangeability aspects of headlamp light sources for manufacturing purposes. For

replacement light sources to be designated as acceptable replacements, the replacement light sources are required to comply with the dimensional and performance information in the docket for its type. A manufacturer may also request modification of a light source for which information has previously been placed in the public docket. The information helps to standardize headlamp bulbs for performance interchangeability.

Affected Public: This information collection affects manufacturers of a motor vehicles, original equipment headlamps, or original equipment headlamp replaceable light sources, which intend to manufacture a replaceable light source as original equipment or to incorporate a replaceable light source in its headlamps or motor vehicles.

Number of respondents: 1 annually.

Frequency: On Occasion.

Estimated Total Annual Burden Hours: 4 hours.

NHTSA estimates that compiling and submitting the required information will take, on average, 4 hours per submission. NHTSA estimates, based on past submissions, that the agency will receive approximately 1 submission per year. Therefore, NHTSA estimates the total burden associated with this information collection to be 4 hours per year.

NHTSA estimates the labor cost associated with this collection of information by (1) applying the appropriate average hourly labor rate published by the Bureau of Labor Statistics (BLS), (2) dividing by 0.702 [1] (70.2%), for private industry workers to obtain the total cost of compensation, and (3) multiplying by the estimated burden hours for each respondent type. NHTSA estimates the hourly cost associated with compiling and submitting documentation under part 564 to be $60.26 [2] per hour using the mean hourly wage estimate published by BLS for compliance officers in the motor vehicle manufacturing industry (Standard Occupational Classification # 13–1041). Therefore, NHTSA estimates that the total labor cost associated with 564 submissions is $241.04 per submission for a total of $241.04 per year for all submissions. Table 1 below provides a summary of the estimated burden hours and labor costs associated with those submissions.

TABLE 1—BURDEN ESTIMATES

Annual number of respondents	Annual submissions	Estimated burden per submission (hours)	Average hourly labor cost	Labor cost per submission	Total burden hours	Total labor costs
1	1	4	$60.26	$241.04	4	$241.04

Estimated Total Annual Burden Cost: $0.

NHTSA estimates that there are no costs to respondents other than labor costs associated with the burden hours.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35; as amended, 49 CFR 1.95 and DOT Order 1351.29.

Ryan R. Posten,

Associate Administrator, Rulemaking.

[FR Doc. 2022–16023 Filed 7–25–22; 8:45 am]

BILLING CODE 4910–59–P

[1] *See* Table 1. Employer Costs for Employee Compensation by ownership (Mar. 2020), available at *https://www.bls.gov/news.release/archives/ecec_06182020.pdf* (accessed March 11, 2022).

[2] The hourly wage is estimated to be $42.30 per hour. National Industry-Specific Occupational Employment and Wage Estimates NAICS 336100—Motor Vehicle Manufacturing, May 2020, *https://www.bls.gov/oes/2020/may/naics4_336100.htm,* (accessed August 20, 2021). The Bureau of Labor Statistics estimates that wages represent 70.4 percent of total compensation to private workers, on average. Therefore, NHTSA estimates the total hourly compensation cost to be $60.09.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0042]

Agency Information Collection Activities; Notice and Request for Comment; Consolidated Child Restraint System Registration for Defect Notifications and Labeling

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for extension of a currently approved information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for an extension of a currently approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from 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 reinstatement of previously approved collections. This document describes a collection of information for which NHTSA intends to seek OMB approval and solicits public comments on continuation of the requirements for the collection of information entitled ''Consolidated Child Restraint System Registration for Defect Notifications and Labeling'' (OMB Control Number: 2127–0576) and the accuracy of the agency's revised estimates of the burden of the information collections.

DATES: Comments must be submitted on or before September 26, 2022.

ADDRESSES: You may submit comments identified by the Docket No. NHTSA–2022–0042 through any of the following methods:

- *Electronic Submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9

a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and 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. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Cristina Echemendia, U.S. Department of Transportation, NHTSA, 1200 New Jersey Avenue SE, West Building, Room W43–447, NRM–130, Washington, DC 20590. Cristina Echemendia's telephone number is 202–366–6345. Please identify the relevant collection of information by referring to its OMB Control Number (2127–0576).

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before an agency submits a proposed collection of information to OMB for approval, it must first 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 regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (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) how to enhance the quality, utility, and clarity of the information to be collected; and (d) 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 for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: ''Consolidated Child Restraint System Registration for Defect Notifications and Labeling.''

OMB Control Number: 2127–0576.

Form Number(s): NHTSA 1053A, NHTSA 1053B.

Type of Request: Extension of a currently approved collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: This information collection provides that manufacturers of child restraint systems (CRSs): (1) produce registration cards, labels and printed instructions (brochures), (2) collect CRS owner registration information, and (3) create and keep registration records so that, in the event of a safety recall, manufacturers can provide direct notification to owners. Child restraint manufacturers are required to provide an owner's registration card for purchasers of child safety seats in accordance with title 49 of the Code of Federal Regulations (CFR), part 571—section 213, ''Child restraint systems.'' The registration card is perforated into two-parts (see Figures 1 and 2). The top part contains a message and suitable instructions to be retained by the purchaser. The bottom part is to be returned to the manufacturer by the purchaser. The bottom part includes prepaid return postage, the pre-printed name/address of the manufacturer, the pre-printed model and date of manufacture, and spaces for purchasers to fill in their name and address. Optionally, child restraint manufacturers are permitted to add to the registration form: (a) Specified statements informing child restraint system (CRS) owners that they may register online; (b) the internet address for registering with the company; (c) revisions to statements reflecting use of the internet to register; and (d) a space for the consumer's email address. For those CRS owners with access to the internet, online registration may be a preferred method of registering a CRS.

In addition to the registration card supplied by the manufacturer, NHTSA has implemented a CRS registration system to assist those individuals who have either lost the registration card that came with the CRS or purchased a previously owned CRS. Upon the owner's request, NHTSA provides a substitute registration form that can be obtained either by mail or from the internet [1] (see Figure 3). When the completed registration is returned to the agency, it is then submitted to the CRS manufacturer. In the absence of a substitute registration system, many owners of child passenger safety seats, especially any second-hand owners, might not be notified of safety defects and non-compliances, and would not have the defects and non-compliances remedied.

Child seat owner registration information is retained in the event that owners need to be contacted for defect recalls or replacement campaigns. Chapter 301 of title 49 of the United States Code specifies that if either NHTSA or a manufacturer determines that motor vehicles or items of motor vehicle equipment contain a defect that relates to motor vehicle safety or fail to comply with an applicable Federal Motor Vehicle Safety Standard, the manufacturer must notify owners and purchasers of the defect or noncompliance and must provide a remedy without charge. In title 49 of the Code of Federal Regulations (CFR), part 577, defect and noncompliance notification for equipment items, including child restraint systems, must be sent by first class mail to the most recent purchaser known to the manufacturer.

Child restraint manufacturers are also required to provide printed instructions in a brochure containing step-by-step information on how the restraint is to be used. Without proper use, the effectiveness of these systems is greatly diminished. Each child restraint system must also have a permanent label. A permanently attached label gives ''quick look'' information on whether the restraint meets the safety requirements, recommended installation and use, and warnings against misuse. CRSs equipped with internal harnesses to restrain children, and with components to attach to a child restraint anchorage system, are also required to be labeled with a child weight limit for using the lower anchors to attach the child restraint to the vehicle. The child weight limit depends upon the weight of the CRS.

Description of the Need for the Information and Proposed Use of the Information: CRS manufacturers are

[1] *https://www.nhtsa.gov/equipment/car-seats-and-booster-seats#car-seat-registration.*

required to label each CRS and provide brochures with safety information and instructions on the proper use of the restraint. Such information would mitigate the risk of misuse and consequently reduce injuries to and fatalities of children in crashes. This collection supports the Department of Transportation's (DOT) strategic goal for safety, by working towards the elimination of transportation related deaths and injuries involving children.

FMVSS No. 213 requires that each CRS has an owner registration form attached. It permits information regarding online product registration to be included on the owner registration form required under the standard. This enhances the opportunity for restraint owners to register their CRSs online, which may increase registration rates and the effectiveness of recall campaigns. Manufacturers are also permitted to supplement (but not replace) recall notification via first-class mail with email notification, which increases the likelihood that owners learn of a recall. Manufacturers are also required to include a U.S. telephone number on a CRS label for the purpose of enabling consumers to register their products by telephone.

Increasing CRS registrations is an important part to protecting young children and infants. By registering CRSs, product manufacturers will to able to directly contact owners in the event of any safety recalls.

Affected Public: Businesses, Individual Consumers.

Estimated Number of Respondents: 38 Manufacturers, 2,835,200 Consumers.

Frequency: On occasion.

Estimated Total Annual Burden Hours: 109,939 hours.

The total burden hours for this collection consist of: (1) the hours spent by consumers filling out the registration form, (2) the hours spent collecting registration information and (3) the hours spent determining the maximum allowable child weight for lower anchor use and adding the information to the existing label and instruction manual.

(1) *Annual Burden for filling out registration card.* NHTSA estimates that 16,000,000 CRSs are currently sold each year by 38 CRS manufacturers. Of the CRSs sold each year, NHTSA estimates that 2,369,660 are registered using registration cards and 465,540 are registered online. A consumer spends approximately 60 seconds (1 minute) filling out the registration form. The estimated annual number of burden hours for consumers to fill out the registration form is 47,253 hours (= 2,835,200 × (60 seconds/3,600 seconds/hour)).

(2) *Annual Burden for Reporting (collecting registration information).* Manufacturers must spend about 90 seconds (1.5 min) to enter the information from each returned registration card; while, online registrations are considered to have no burden for the manufacturer, as the information is entered by the purchaser. Therefore, the estimated annual number of burden hours for CRS registration information collection is 59,242 hours (= 2,369,660 × (90 seconds/3,600 seconds/hour)).

(3) *Annual Burden for Reporting (determining maximum allowable child weight).* About 12,400,000 of the CRSs sold each year are equipped with internal harnesses. About half of the CRSs equipped with internal harnesses sold annually (6,200,000 = 12,400,000 × 0.5) would require a label with the maximum allowable child weight for using the lower anchors. Manufacturers must spend about 2 seconds to determine the maximum allowable child weight for lower anchor use and to add the information to the existing label and instruction manual. Therefore, the total annual burden hours for the information on the maximum allowable child weight in the existing label and instruction manual is 3,444 hours (= 6,200,000 × (2 seconds/3,600 seconds/hour)).

The estimated total annual number of burden hours is 109,939 (= 47,253 + 59,242 + 3,444) hours. The total estimated hour burden increased from 99,330 hours to 109,939 hours (a 10,609-burden hour increase). The increase in burden is due to an increase in CRS sales. In 2018, NHTSA estimated that approximately 14,500,000 CRSs are sold each year while NHTSA's estimate in 2022 increased to 16,000,000 CRSs.

Estimated Total Annual Burden Cost: $8,000,000.

The total burden cost for this collection consist of printing and material costs of labels and registration cards.

Printing and Material Costs of Labels and Registration Cards

The total annual cost to the respondents is estimated to be $8,000,000. NHTSA estimates that the printing and material cost of $0.20 per CRS labels and $0.30 per CRS registration card. The total annual cost to respondents is calculated by multiplying the printing and material cost ($0.50 = $0.20 + $0.30) by the estimated 16,000,000 responses (CRSs produced) per year ($0.50 × 16,000,000). The total estimated annual burden costs are detailed in the table below:

Number of CRS produced annually	Printing and material cost per CRS—labels	Printing and material cost per CRS—registration card	Annual printing and material cost
16,000,000	$0.20	$0.30	$8,000,000.00

The total estimated burden cost increased from $0 to $8,000,000 (a $8,000,000 burden cost increase). The increase in burden is due to the addition of printing and material costs for labels and registration cards which had not been taken into consideration in the past.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

BILLING CODE 4910–59–P

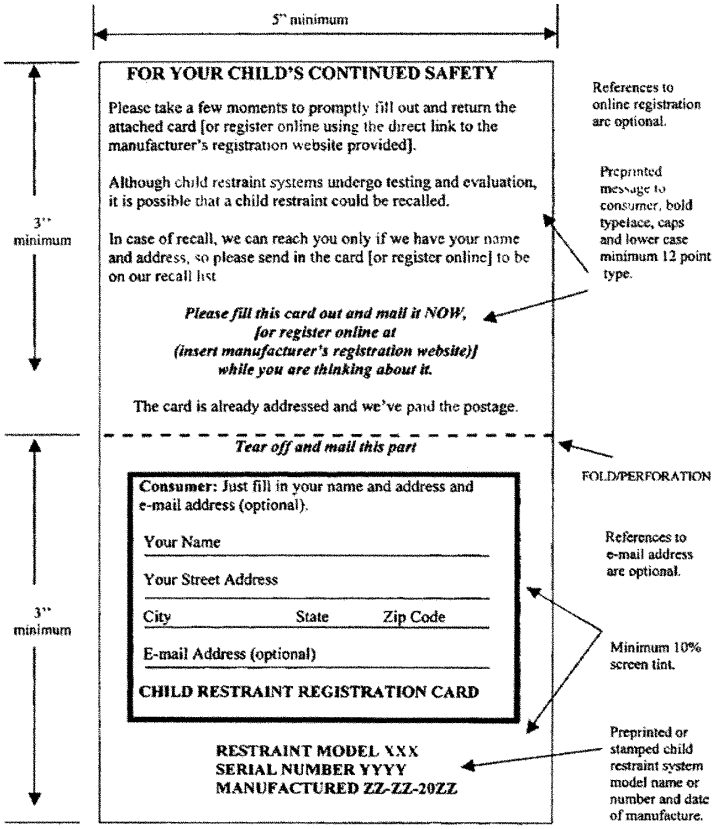

Figure 1 – Registration form for child restraint systems – product identification number and purchaser information side

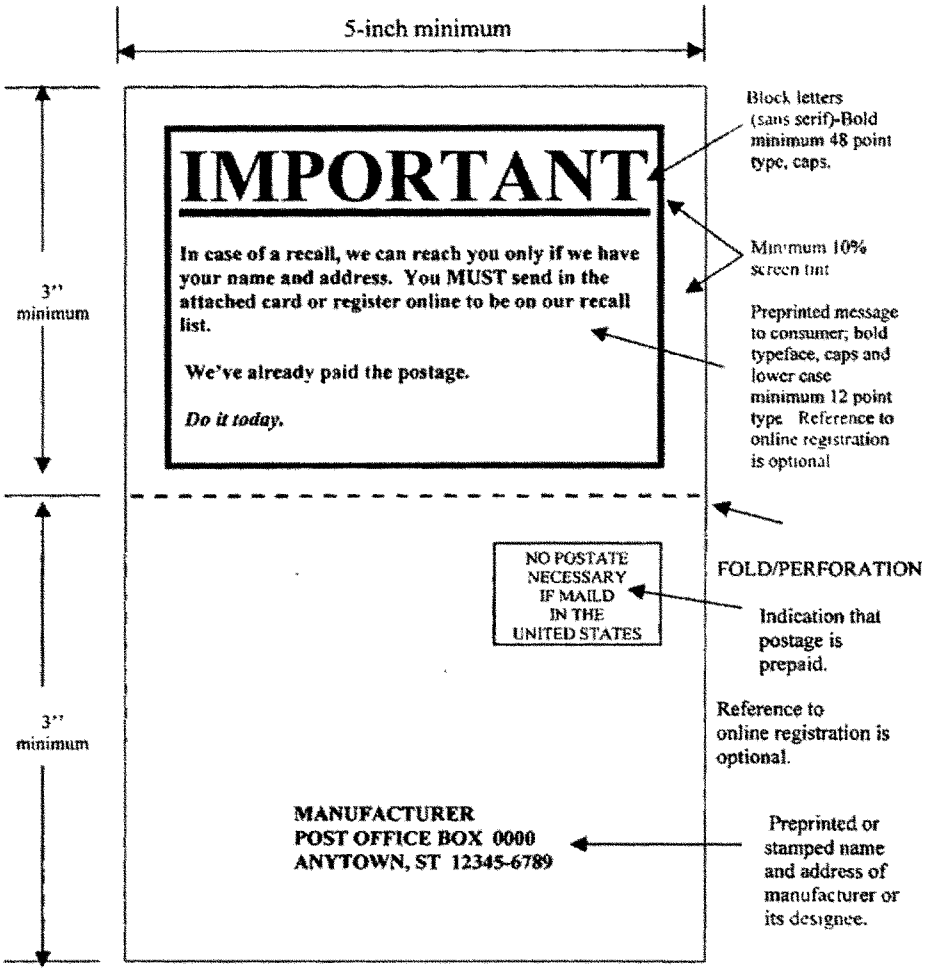

Figure 2 – Registration form for child restraint systems – address side

CHILD SAFETY SEAT REGISTRATION FORM
FOR YOUR CHILD'S CONTINUED SAFETY

Although child safety seats undergo testing and evaluation, it is possible that your child seat could be recalled. In case of a recall it is important that the manufacturer be able to contact you as soon as possible so that your seat can be corrected.

All child safety seats manufactured since March 1993 have a registration form so that owners can provide their names/addresses to the manufacturer. In case of a safety recall, the manufacturer can use that information to send recall letters to owners. Also, child safety seat manufacturers have agreed to maintain owner names/addresses for child safety seats manufactured before March 1993, so they can notify those consumers in the event of a future safety recall. However, in order for the manufacturer to know which child safety seat you own, all of the information on the lower half of this page must be provided.

If you would like the National Highway Traffic Safety Administration (NHTSA) to give your name and address to the manufacturer of your child safety seat, so that you can be notified of any future safety recalls regarding your child safety seat, fill out this form. Please type or print clearly, sign and mail this postage-paid, pre-addressed form.

If you have any questions, or need help with any child safety seat or motor vehicle safety issue, call the U.S. Department of Transportation's toll-free Vehicle Safety Hotline at 1-888-424-9393 (Washington DC AREA RESIDENTS, 202-366-0123).

Your Name:_____ Telephone_____

Your Street Address_____

City:_____, State:_____ Zip Code:_____

IMPORTANT: The following information is essential and can be found on labels on your child seat.

Child Seat Manufacturer:_____

Child Seat Model Name & Number:_____

Child Seat Date of Manufacture:_____

I AUTHORIZE NHTSA TO PROVIDE A COPY OF THIS REPORT TO THE CHILD SAFETY SEAT MANUFACTURER.

SIGNATURE:_____ **DATE:**_____

Please mail to:
U.S. Department of Transportation
National Highway Traffic Safety Administration
DOT Vehicle Safety Hotline
400 7th Street, SW
Washington, DC 20590

The Privacy Act of 1974 - Public Law 93-579, As Amended: This information is requested pursuant to the authority vested in the National Highway Traffic Safety Act and subsequent amendments. You are under no obligation to respond to this questionnaire. Your response can be used to assist the NHTSA in determining whether a manufacturer should take appropriate action to correct a safety defect. If the NHTSA proceeds with administration enforcement or litigation against a manufacturer, your response, or sanitized summary thereof, may be used in support of the agency's action.

Figure 3 – Illustration of a child restraint system registration form

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2022–16022 Filed 7–25–22; 8:45 am]

BILLING CODE 4910–59–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Gains and Losses From Section 1256 Contracts and Straddles

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments

concerning gains and losses from section 1256 contracts and straddles.

DATES: Written comments should be received on or before September 26, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov*. Include OMB control number 1545–0644 or Gains and Losses From Section 1256 Contracts and Straddles, in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *Kerry.L.Dennis@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Gains and Losses From Section 1256 Contracts and Straddles.

OMB Number: 1545–0644.

Form Number: 6781.

Abstract: Form 6781 is used by taxpayers in computing their gains and losses on Internal Revenue Code section 1256 contracts under the marked-to-market rules and gains and losses under Code section 1092 from straddle positions. The data is used to verify that the tax reported accurately reflects any such gains and losses.

Current Actions: There is no change to the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals.

Estimated Number of Respondents: 5,684.

Estimated Time Per Respondent: 13.95 hours.

Estimated Total Annual Burden Hours: 79,292 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 20, 2022.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2022–15971 Filed 7–25–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

National Research Advisory Council, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the National Research Advisory Council will hold a meeting on Wednesday, September 7, 2022, by Teams. The teleconference number is 1–872–701–0185, conference ID 723 601 208 # or the meeting link is *https://teams.microsoft./com/l/meetup-join/19%3ameeting_YTM4OWM5O/DItMThkYy00YzBiLThi/YzctZTdiMjll/OTVlNWEz%40thread./v2/0?/context=%7b%22Tid/%22%3/a%22e95f1b23-abaf-45ee-821d-b7ab251/ab3bf%22%2/c%22Oid%22%3/a%22121a3c2b-ae37-46ab-a12a-fa7b555533ae%22%7d*. The meeting will convene at 11:00 a.m. and end at 2:00 p.m. Eastern daylight time. This meeting is open to the public.

The purpose of the National Research Advisory Council is to advise the Secretary on research conducted by the Veterans Health Administration, including policies and programs targeting the high priority of Veterans' health care needs.

On September 7, 2022, the agenda will include follow up discussion of diversity, equity, and inclusion activities; overview of VA Artificial Intelligence Program; discussion of subcommittee activities and updates on the Research Enterprise Initiative. No time will be allocated at this meeting for receiving oral presentations from the public. Members of the public wanting to attend, have questions or presentations to present may contact Rashelle Robinson, Designated Federal Officer, Office of Research and Development (14RD), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, at 202–443–5768, or *Rashelle.robinson@va.gov no later than close of business on September 2, 2022.* All questions and presentations will be presented during the public comment section of the meeting. Any member of the public seeking additional information should contact Rashelle Robinson at the above phone number or email address noted above.

Dated: July 21, 2022.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–16014 Filed 7–25–22; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 87 Tuesday,

No. 142 July 26, 2022

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services
42 CFR Part 405, 410, 411, et al.
Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 412, 413, 416, 419, and 424

[CMS–1772–P]

RIN 0938–AU82

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (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 Calendar Year (CY) 2023 based on our continuing experience with these systems. In this proposed rule, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REH) Program. We are also proposing updates to the requirements for Organ Acquisition, Rural Emergency Hospitals, Prior Authorization, and Overall Hospital Quality Star Rating. We are establishing a new provider type for rural emergency hospitals (REHs), and we have proposals regarding payment policy, quality measures, and enrollment policy for REHs. Finally, we are soliciting comments on the use of CMS data to drive competition in healthcare marketplaces, and an alternative methodology for counting organs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 13, 2022.

ADDRESSES: In commenting, please refer to file code CMS–1772–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

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–1772–P, P.O. Box 8010, Baltimore, MD 21244–1810.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1772–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Elise Barringer, *Elise.Barringer@cms.hhs.gov* or 410–786–9222.

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 Scott Talaga via email at *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Cyra Duncan via email *Cyra.Duncan@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at *Chuck.Braver@cms.hhs.gov*.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email at *AuSha.Washington@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Hospital Inpatient Quality Reporting Program—Administration Issues, contact Julia Venanzi at *Julia.Venanzi@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Shaili Patel via email *Shaili.Patel@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Janis Grady via email *Janis.Grady@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Emily Yoder via email at *Emily.Yoder@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik at *Abigail.Cesnik@cms.hhs.gov*.

Mental Health Services Furnished Remotely by Hospital Staff To Beneficiaries in Their Homes, Emily Yoder at *Emily.Yoder@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

OPPS Brachytherapy, contact Scott Talaga via email at *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 via email at *Erick.Chuang@cms.hhs.gov*, or Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*, or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*, or Gil Ngan via email at *Gil.Ngan@cms.hhs.gov*, or Cory Duke via email at *Cory.Duke@cms.hhs.gov*, or Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov*.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Packaged Items/Services, contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at *Marina.Kushnirova@cms.hhs.gov*.

Organ Acquisition Payment Policies, contact Katie Lucas via email at *Katherine.Lucas@cms.hhs.gov*, or Mandy Michael via email at *Amanda.Michael@cms.hhs.gov*, or Kellie Shannon via email at *Kellie.Shannon@cms.hhs.gov*.

Outpatient Department Prior Authorization Process, contact Yuliya Cook via email at *Yuliya.Cook@cms.hhs.gov*.

Overall Hospital Quality Star Rating, contact Tyson Nakashima via email at *Tyson.Nakashima@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*.

Request for Information on Use of CMS Data to Drive Competition in Healthcare Marketplaces, contact Terri Postma via email at *Terri.Postma@cms.hhs.gov*.

Rural Emergency Hospital Provider Enrollment, contact Frank Whelan via email at *Frank.Whelan@cms.hhs.gov*.

Rural Emergency Hospital Quality Reporting (REHQR) Program Issues, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Rural Emergency Hospitals (REH) Physician Self-Referral Law Update Issues, contact Lisa O. Wilson via email at *Lisa.Wilson2@cms.hhs.gov* or Matthew Edgar via email at *Matthew.Edgar@cms.hhs.gov*.

Skin Substitutes, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Use of the Medicare Outpatient Observation Notice by REHs, contact Nishamarie Sherry via email at *Nishamarie.Sherry@cms.hhs.gov* or Janet Miller via email at *Janet.Miller@cms.hhs.gov*.

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at *OutpatientPPS@cms.hhs.gov*.

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at *ASCPPS@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 website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the Internet on the CMS Website

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 website. The Addenda relating to the OPPS are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices*.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2021 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR and Defense Federal Acquisition Regulations (DFAR) apply.

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we propose 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, 2023. 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 of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. 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. We are also proposing updates to the requirements for Organ Acquisition, Prior Authorization, and Overall Hospital Quality Star Rating. We are also proposing new regulatory requirements to codify payment policy, quality measures, and enrollment policy for Rural Emergency Hospitals. Finally, we are soliciting comments on the use of CMS data to drive competition in healthcare marketplaces, and a Request for Information on an alternative methodology for counting organs.

2. Summary of the Major Provisions

• *OPPS Update:* For 2023, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.7 percent. This proposed increase factor is based on the proposed hospital inpatient market basket percentage increase of 3.1 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.4 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2023 would be approximately $86.2 billion, an increase of approximately $6.2 billion compared to estimated CY 2022 OPPS payments.

We propose to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

• *Data used in CY 2023 OPPS/ASC Ratesetting:* To set CY 2023 OPPS and ASC payment rates, we would normally use the most updated claims and cost report data available. The best available claims data is the most recent set of data which would be from 2 years prior to the calendar year that is the subject of rulemaking. Therefore, we are proposing to use the CY 2021 claims data to set CY 2023 OPPS and ASC rates. However, cost report data usually lags the claims data by a year and CMS believes that the CY 2020 cost report data are not the best overall approximation of expected outpatient hospital services as the majority of the cost reports we would typically use for CY 2023 rate setting have cost reporting periods that overlap with parts of the CY 2020 Public Health Emergency (PHE). In order to mitigate the impact of some of the temporary changes in hospitals cost report data from CY 2020, we propose to use cost report data from the June 2020 extract from Healthcare Cost Report Information System (HCRIS), which includes cost report data from prior to the PHE. This is the same cost report extract we used to set OPPS rates for CY 2022. We believe using the CY 2021 claims data with cost reports data through CY 2019 (prior to the PHE) for CY 2023 OPPS ratesetting is the best approximation of expected costs for CY 2023 hospital outpatient services for ratesetting purposes. As a result, CMS is proposing to use CY 2021 claims data with cost reports with cost reporting periods prior to the PHE to set CY 2023 OPPS and ASC payment system rates.

• *Partial Hospitalization Update:* For CY 2023, we propose to calculate the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs consistent with our existing methodology, except that while we propose to use the latest available CY 2021 claims data, we propose to continue to use the cost data that was available for the CY 2021 rulemaking.

• *Changes to the Inpatient Only (IPO) List:* For 2023, we propose to remove ten services from the Inpatient Only list.

• 340B-*Acquired Drugs:* For CY 2023, we formally propose at this time to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. This proposal is in accordance with the policy choices and calculations that CMS made in the months leading up to publication of this proposed rule before the Supreme Court issued its decision in *American Hospital Association* v. *Becerra* (Docket 20–1114). However, we note that, in light of the Supreme Court's recent decision in *American Hospital Association* v. *Becerra,* we fully anticipate applying a rate of ASP + 6 percent to such drugs and biologicals in the final rule for CY 2023 and making a corresponding decrease to the conversion factor consistent with the OPPS statute and our longstanding policy that this adjustment is made in a budget neutral manner. We are still evaluating how to apply the Supreme Court's recent decision to prior calendar years. In that decision, the Court summarized the parties' arguments regarding budget neutrality and stated that, ''[a]t this stage, we need not address potential remedies.'' We are interested in public comments on the best way to craft any potential remedies affecting cost years 2018–2022 given that the Court did not resolve that issue.

• *Device Pass-Through Payment Applications:* For CY 2023, we received 8 applications for device pass-through payments. We solicit public comment on these applications and will make final determinations on these applications in the CY 2023 OPPS/ASC final rule. Beginning for OPPS device pass-through applications received on or after January 1, 2023, we propose to publicly post online the completed application forms and related materials that we receive from applicants, excluding certain copyrighted or other materials that applicants indicate cannot otherwise be released to the public.

• *Cancer Hospital Payment Adjustment:* For CY 2023, we propose to continue providing additional payments to cancer hospitals so that a 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, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we proposed to use a target PCR of 0.89 to determine the CY 2023 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

• *ASC Payment Update:* For CYs 2019 through 2023, we propose to adopt a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2023, we propose to increase payment rates under the ASC payment system by 2.7 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a hospital market basket percentage increase of 3.1 percent reduced by a productivity adjustment of 0.4 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2023 would be approximately 5.4 billion, an increase of approximately 130 million compared to estimated CY 2022 Medicare payments.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2023, we propose to add one procedure, a lymph node biopsy or excision, to the ASC CPL based upon existing criteria at § 416.166.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program measure set, we are proposing to: (1) add a data validation targeting criterion to our existing four targeting criteria that reads: ''Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters,'' beginning with the CY 2023 reporting period/CY 2025 payment determination; (2) align patient encounter quarters with the calendar year, beginning with the CY 2024 reporting period/CY 2026 payment determination; and (3) change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP–31) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination. We are requesting comment on the future readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) measure or another volume indicator in the Hospital OQR Program.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program measure set, we are proposing to change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination. We are also requesting comment on: (1) the potential future implementation of a measures value pathways approach in the ASCQR Program; (2) the status and feasibility of interoperability initiatives in the ASCQR Program; and (3) the potential readoption of the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC–7) measure or another volume indicator in the ASCQR Program. We are also proposing to suspend mandatory implementation of the ASC–11 measure.

• *Organ acquisition payment policy:* We are issuing a Request for Information on counting Medicare organs for use in calculating Medicare's share of organ acquisition costs, rather than making a proposal, and will use the information to inform potential future rulemaking. Also, we propose to exclude research organs from the calculation of Medicare's share of organ acquisition costs and require a cost offset; these proposals would help ensure that Medicare does not share in the cost of research, and would lower the cost of procuring and providing research organs to the research community. Finally, we propose to cover as organ acquisition costs certain hospital costs typically incurred when donors die from cardiac death, to promote organ procurement and enhance equity.

• *Rural Emergency Hospitals (REH): Provider Enrollment:* We are outlining provider enrollment requirements for REHs. The most important of these is that REHs must comply with all applicable provider enrollment provisions in 42 CFR part 424, subpart P in order to enroll in Medicare.

• *Rural Emergency Hospitals (REH) Physician Self-Referral Law Update:* We propose (1) a new exception for ownership or investment interests in an REH; and (2) revisions to certain existing exceptions to make them applicable to compensation arrangements to which an REH is a party.

• *Rural Emergency Hospital Quality Reporting (REHQR) Program:* For the REHQR Program, we are proposing to require a QualityNet account and Security Official (SO) requirement in line with other quality programs for purposes of data submission and access of facility level reports. We are also requesting information on: (1) measures recommended by the National Advisory Committee on Rural Health and Human Services and additional suggested measures for the REHQR Program, and (2) and comments on rural telehealth, behavioral and mental health, and maternal health services.

• *Overall Hospital Quality Star Ratings:* For the Overall Hospital Quality Star Ratings, we are: (1) providing information on the previously finalized policy for inclusion of quality measure data from Veteran's Health Administration hospitals; (2) proposing to amend § 412.190(c) to state the use of publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior 12 months (instead of the ''prior year''); and (3) conveying that although CMS intends to publish Overall Hospital Quality Star Ratings in 2023, we may apply the suppression policy discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027) should data analysis demonstrate that the COVID–19 Public Health Emergency (PHE) substantially affects the underlying measure data.

• *REH Payment Policy:* Section 125 of the Consolidated Appropriations Act of 2021 (CAA) established a new provider type called Rural Emergency Hospitals (REHs), effective January 1, 2023.

REHs are facilities that convert from either a critical access hospital (CAH) or a rural hospital (or one treated as such under section 1886(d)(8)(E) of the Social Security Act) with less than 50 beds, and that do not provide acute care inpatient services with the exception of post-hospital extended care services furnished in a unit of the facility that is a distinct part licensed as a skilled nursing facility. By statute, REH services include emergency department services and observation care and, at the election of the REH, other outpatient medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking.

By statute, covered outpatient department services provided by REHs will receive an additional 5 percent payment for each service. Beneficiaries will not be charged a copayment on the additional 5 percent payment.

We are proposing to consider all covered outpatient department services, other than inpatient hospital services as described in section 1833(t)(1)(B)(ii), that would otherwise be paid under the OPPS as REH services. REHs would be paid for furnishing REH services at a rate that is equal to the OPPS payment rate for the equivalent covered outpatient department service increased by 5 percent. We are also proposing that REHs may provide outpatient services that are not otherwise paid under the OPPS (such as services paid under the Clinical Lab Fee Schedule) as well as post-hospital extended care services furnished in a unit of the facility that is a distinct part of the facility licensed as a skilled nursing facility; however, these services would not be considered REH services and therefore would be paid under the applicable fee schedule and would not receive the additional 5 percent payment increase that CMS proposes to apply to REH services.

Finally, we are proposing that REHs would also receive a monthly facility payment. After the initial payment is established in CY 2023, the payment amount will increase in subsequent years by the hospital market basket percentage increase.

• *Proposed Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process:* We propose to add facet joint interventions as a category of services to the prior authorization process for hospital outpatient departments beginning for dates of service on or after March 1, 2023.

• *Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes:* For CY 2023, CMS is proposing to consider mental health services furnished remotely by hospital staff using communications technology to beneficiaries in their homes as covered outpatient department services payable under the OPPS and would create OPPS-specific coding for these services.

We are proposing to require an in-person service within 6 months prior to the initiation of the remote service and then every 12 months thereafter, that exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that more frequent visits are also allowed under our policy, as driven by clinical needs on a case-by-case basis. We are also proposing that audio-only interactive telecommunications systems may be used to furnish these services in instances where the beneficiary is not capable of, or does not consent to, the use of two-way, audio/video technology.

• *Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients:* For CY 2023, to improve clarity, we propose to replace cross-references at § 410.27(a)(1)(iv)(A) and (B) and § 410.28(e) to the definitions of general and personal supervision at § 410.32(b)(3)(i) and (iii) with the text of those definitions. We also propose to revise § 410.28(e) to clarify that certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) may supervise the performance of diagnostic tests to the extent they are authorized to do so under their scope of practice and applicable State law.

• *Exemption of Rural Sole Community Hospitals (SCH) from the Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs):* We are proposing to exempt rural Sole Community Hospitals (rural SCHs) from the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines).

• *Proposed Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators:* As discussed in section X.H of the preamble of this proposed rule, the Biden-Harris Administration has made it a priority to ensure America is prepared to continue to respond to COVID–19, and to combat future pandemics. To improve hospital preparedness and readiness for future threats, we are proposing to provide payment adjustments to hospitals under the IPPS and OPPS for the additional resource costs they incur to acquire domestic NIOSH-approved surgical N95 respirators. These surgical respirators, which faced severe shortage at the onset of the COVID–19 pandemic, are essential for the protection of beneficiaries and hospital personnel that interface with patients. The Department of Health and Human Services (HHS) recognizes that procurement of domestic NIOSH-approved surgical N95 respirators, while critical to pandemic preparedness and protecting health care workers and patients, can result in additional resource costs for hospitals. The proposed payment adjustments would account for these additional resource costs.

We believe the proposed payment adjustments would help achieve a strategic policy goal, namely, sustaining a level of supply resilience for surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We are proposing that the payment adjustments would commence for cost reporting periods beginning on or after January 1, 2023.

3. Summary of Costs and Benefits

In section XXIII of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 84 in section XXIII.C of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2023 compared to all estimated OPPS payments in CY 2022. We estimate that the policies in this proposed rule would result in a 2.9 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2023, including beneficiary cost-sharing, to the approximately 3,502 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $1.8 billion compared to CY 2022 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate an 8.4 percent decrease in CY 2023 payments to CMHCs relative to their CY 2022 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2023 IPPS proposed rule wage indexes would result in no change for urban hospitals under the OPPS and no change for rural hospitals. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C of this proposed rule.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2023 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural hospital payment adjustments. While we are implementing the reduction to the cancer hospital payment adjustment for CY 2023 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, the target payment-to-cost ratio (PCR) for CY 2023 is 0.89, equivalent to the 0.89 target PCR for CY 2022, and therefore has no budget neutrality adjustment.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2023 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.7 percent and applying that increase factor to the conversion factor for CY 2023. We note that the following estimated changes are based on the formal proposal discussed in V.B of this proposed rule. However, we are making available online alternative impact tables and other supporting data associated with the alternative policy for 340B-acquired drugs.

As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals would experience an increase in payments of approximately 3.0 percent and that rural hospitals would experience an increase in payments of 2.6 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals will experience an increase in payments of 3.2 percent, minor teaching hospitals would experience an increase in payments of 3.0 percent, and major teaching hospitals would experience an increase in payments of 2.6 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would

experience an increase of 2.8 percent in payments, while hospitals with government ownership would experience an increase of 2.8 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 3.5 percent in payments.

e. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2023 payment rates, compared to estimated CY 2022 payment rates, generally ranges between an increase of 1 and 6 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates would increase payments by $130 million under the ASC payment system in CY 2023.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the 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 OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS 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 OPPS. The following Acts made additional changes to the OPPS: 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 (MCTRJCA, 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, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; and the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020.

Under the OPPS, we generally 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, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care 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, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, 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 website 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 expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) 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 Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise 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;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 20, 2020, for a 2-year period.

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 website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisorPanelAmbulatoryPaymentClassificationGroups.html.*

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 22, 2021. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81

FR 31941). In CY 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (83 FR 3715). As published in this notice, CMS is accepting nominations on a continuous basis.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 23, 2021, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *http://facadatabase.gov*.

F. Public Comments Received on the CY 2022 OPPS/ASC Final Rule With Comment Period

We received approximately 13 timely pieces of correspondence on the CY 2022 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 16, 2021 (86 FR 63458)

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Use of CY 2021 Data in the CY 2023 OPPS Ratesetting

We primarily use two data sources in OPPS ratesetting: claims data and cost report data. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available full year of claims data would be the data from the year 2 years prior to the calendar year that is the subject of the rulemaking. As discussed in further detail in section X.C of this proposed rule, unlike CY 2020 claims data, we do not believe there are overwhelming concerns with CY 2021 claims data as a result of the COVID–19 PHE. Therefore, as discussed in further detail in section X.C of this proposed rule, we propose to use CY 2021 claims data and the data components related to it in establishing the CY 2023 OPPS.

b. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2023 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2023, and before January 1, 2024 (CY 2023), using the same basic methodology that we described in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63466), using CY 2021 claims data. That is, we propose to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2023, we began with approximately 180 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, 2021, and before January 1, 2022, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 93 million final action claims to develop the proposed CY 2023 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for the CY 2023 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Addendum N to the CY 2023 OPPS/ASC proposed rule (which is available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*) includes the proposed list of bypass codes for CY 2023. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2021 and, therefore, includes codes that were in effect in CY 2021 and used for billing. We propose to retain deleted bypass codes on the proposed CY 2023 bypass list because these codes existed in CY 2021 and were covered OPD services in that period, and CY 2021 claims data were used to calculate proposed CY 2023 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 propose to add for CY 2023 are identified by asterisks (*) in the fourth column of Addendum N.

c. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2023, we propose 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. However, roughly half of the cost reports we would typically use for CY 2023 ratesetting purposes are from cost reporting periods that overlap with parts of CY 2020. When utilizing this cost report data, more than half of the APC geometric mean costs increased by more than 10 percent relative to estimates based on prior ratesetting cycles. While some of this increase may be attributable to changes that will continue into CY 2023, other aspects of those changes may be more specific to the COVID–19 PHE. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), we

described how CY 2020 claims data were too influenced by the COVID–19 PHE to be utilized for setting CY 2022 OPPS payment rates. After reviewing the cost report data from the December 2021 HCRIS data set, we believe cost report data that overlap with CY 2020 are also too influenced by the COVID–19 PHE for purposes of calculating the CY 2023 OPPS payment rates. Therefore, in order to mitigate the impact on our ratesetting process from the COVID–19 PHE effects in the CY 2020 cost report data we would typically use for this CY 2023 OPPS/ASC proposed rule, we propose to use cost report data from the June 2020 HCRIS data set, which only includes cost report data through CY 2019 for CY 2023 OPPS/ASC proposed rule and final rule ratesetting purposes. For additional discussion of the data we propose to use in CY 2023 OPPS ratesetting, please see section X.C of this proposed rule.

To calculate the APC costs on which the CY 2023 APC payment rates are based, we propose to calculate hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2021 claims data by comparing these claims data to hospital cost reports available for the CY 2022 OPPS/ASC final rule with comment period ratesetting, which, in most cases, are from CY 2019. For the proposed CY 2023 OPPS payment rates, we propose to use CY 2021 claims processed through December 31, 2021. 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. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2021 (the year of claims data we used to calculate the proposed CY 2023 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2020 Data Specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

In accordance with our longstanding policy, we propose to 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. Additionally, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We have determined that hospitals are routinely reporting a number of nonstandard cost centers in this way and that including this additional data could significantly reduce certain APC geometric mean costs. In particular, we estimate that the additional cost data from nonstandard cost centers would decrease the geometric mean cost of APC 8004 (Ultrasound Composite) by 20 percent, APC 5863 (Partial Hospitalizations (3 or more services) for hospital-based PHPs) by 12 percent and APC 5573 (Level 3 Imaging with Contrast) by 11 percent. In other instances, we note that there are also potential increases in the geometric mean costs of certain APCs, such as APC 5741 (Level 1 Electronic Analysis of Devices), which would increase by 4 percent, APC 5723 (Level 3 Diagnostic Tests and Related Services), which would increase by 2.6 percent, and APC 5694 (Level 4 Drug Administration), which would increase by 2.3 percent.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. Additionally, we are concerned about the significant changes in APC geometric mean costs that our analysis indicates would occur if we were to include such lines. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. For CY 2023, we propose not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction. We are soliciting comment on whether there exist any specific concerns with regards to the accuracy of the data from these nonstandard cost center lines that we would need to consider before including them in future OPPS ratesetting.

For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this proposed rule.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2023. The Hospital OPPS page on the CMS website on which the CY 2023 OPPS/ASC 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, later 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 website, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2021 claims that are used to calculate the proposed payment rates for this CY 2023 proposed rule.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, 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.

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 OPPS payment rates for CY 2023 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*). 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.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN'', which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2023 OPPS, we would continue to remove claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in the CY 2023 OPPS/ASC proposed rule, we refer readers to the claims accounting narrative under supporting documentation for the CY 2023 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

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.

We propose 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, to address the differences in CCRs and to better reflect hospitals' costs, we propose 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 propose to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We propose to calculate the costs upon which the proposed CY 2023 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 using this methodology in CY 2023 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 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 propose 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 propose not to 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 66795 through 66796) for more information about our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C–APC).

We refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website) for the proposed CY 2023 payment rates for blood and blood products (which are generally 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).

For CY 2023, we propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable,

and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2023, except where otherwise indicated, we propose to use the costs derived from CY 2021 claims data to set the proposed CY 2023 payment rates for brachytherapy sources because CY 2021 is the year of data we propose to use to set the proposed payment rates for most other items and services that would be paid under the CY 2023 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D of this proposed rule, we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also propose to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2023 payment rates for brachytherapy sources are included on Addendum B to this proposed rule (which is available via the internet on the CMS website) and identified with status indicator ''U''.

For CY 2018, we assigned status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm². For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm². Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm². In response to comments from stakeholders, we agreed that given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of $1.02 per mm² may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm² for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021 and CY 2022 OPPS/ASC final rules (85 FR 85879 through 85880 and 86 FR 63469) with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm² for HCPCS code C2645 for CY 2021 and for CY 2022.

We did not receive any CY 2021 claims data for HCPCS code C2645. Therefore, we propose to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm² for HCPCS code C2645 for CY 2023.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs, discussed in further detail in section III.D of this proposed rule. For these Low Volume APCs, which have fewer than 100 CY 2021 single claims used for ratesetting purposes in this CY 2023 OPPS/ASC proposed rule, we use up to 4 years of claims data to establish a payment rate for each item or service as we historically have done for low volume services assigned to New Technology APCs. Further, we calculate the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost using all claims for the APC for up to 4 years. For CY 2023, we propose to designate 4 brachytherapy APCs as Low Volume APCs for CY 2023 as these APCs meet our criteria to be designated as a Low Volume APC. For more information on the brachytherapy APCs we are designating as Low Volume APCs, see section III.D of this proposed rule.

We invite stakeholders to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to *outpatientpps@cms.hhs.gov* or by mail to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C–APCs) for CY 2023

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014 but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and

systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). We have gradually added new C–APCs since the policy was implemented beginning in CY 2015, with the number of C–APCs now totaling 69 (80 FR 70332; 81 FR 79584 through 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; and 86 FR 63474).

Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C–APC service when it appears on an outpatient claim with a primary C–APC service.

In the interim final rule with request for comments (IFC) titled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', published on November 6, 2020, we stated that, effective for services furnished on or after the effective date of the IFC and until the end of the PHE for COVID–19, there is an exception to the OPPS C–APC policy to ensure separate payment for new COVID–19 treatments that meet certain criteria (85 FR 71158 through 71160). Under this exception, any new COVID–19 treatment that meets the following two criteria will, for the remainder of the PHE for COVID–19, always be separately paid and will not be packaged into a C–APC when it is provided on the same claim as the primary C–APC service. First, the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID–19, as indicated in section ''I. Criteria for Issuance of Authorization'' of the FDA letter of authorization for the emergency use of the drug or biological product, or the drug or biological product must be approved by FDA for treating COVID–19. Second, the emergency use authorization (EUA) for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by FDA to treat COVID–19 disease and not limit its use to the inpatient setting. For further information regarding the exception to the C–APC policy for COVID–19 treatments, please refer to the November 6, 2020 IFC (85 FR 71158 through 71160).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period 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'';
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission 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 set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C–APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of this final rule with comment period, in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the

requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2023, we propose 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 for ''J1'' and add-on code combinations for CY 2023, along with all of the other final complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*).

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 four 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 assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. 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 (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2''

when they are included on a claim with a ''J2'' service (84 FR 61167). We propose to continue to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' or ''J2'' service assigned to a C–APC.

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified Drugs or Biologicals) From the C–APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the FDA and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies. Since the implementation of the C–APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 has been included in the C–APC payment when these products appear on a claim with a primary C–APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C–APC service is consistent with our C–APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It has been our position that the total payment for the C–APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we have determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWPs when payment for them is packaged with payment for a primary C–APC service. In order to ensure payment for new drugs, biologicals, and radiopharmaceuticals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we propose to exclude any drug, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug, biological, or radiopharmaceutical is included on a claim with a ''J1'' service, which is the status indicator assigned to a C–APC, and a claim with a ''J2'' service, which is the status indicator assigned to comprehensive observation services. Please see OPPS Addendum J for the proposed CY 2023 comprehensive APC payment policy exclusions.

We are also including a corresponding proposal in section XI ''Proposed CY 2023 OPPS Payment Status and Comment Indicators'', to add a new definition to status indicator ''A'' to include unclassified drugs and biologicals that are reportable with HCPCS code C9399. The proposed definition, found in Addendum D1 to this proposed rule, would ensure the MAC prices claims for drugs, biologicals or radiopharmaceuticals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug, biological, or radiopharmaceutical under the OPPS when it appears on the same claim as a primary C–APC service.

(4) Additional C–APCs for CY 2023

For CY 2023, we propose to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we propose to add one C–APC under the existing C–APC payment policy in CY 2023: Proposed C–APC 5372 (Level 2 Urology and Related Services). This APC was selected to be included in this proposed rule because, similar to other C–APCs, this APC includes primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services. Also, similar to other clinical APCs that have been converted to C–APCs, there are higher APC levels (Levels 3–8 Urology and Related Services) within the clinical family or related clinical family of this APC that have previously been converted to C–APCs.

Table 1 below lists the proposed C–APCs for CY 2023. All C–APCs are displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). Addendum J to this proposed rule also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information.

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TABLE 1: PROPOSED CY 2023 C-APCs

C-APC	CY 2023 APC Group Title	Clinical Family	New C-APC
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 and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and 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	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
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 and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5372	Level 2 Urology and Related Services	UROXX	*
5373	Level 3 Urology and Related Services	UROXX	

C-APC	CY 2023 APC Group Title	Clinical Family	New C-APC
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and 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
EVASC = Endovascular Procedures
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

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c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

We propose to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years 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 will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE will 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 OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We propose 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 for CY 2023. In addition, we propose to set the payment rate for composite APC 8010 at the same payment rate that we propose 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 proposed payment rate for composite APC 8010.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, 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 2 below.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2023, we propose 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.

For CY 2023, except where otherwise indicated, we propose to use the costs derived from CY 2021 claims data to set the proposed CY 2023 payment rates. Therefore, for CY 2023, the 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 CY 2021 claims available for this proposed rule that qualify 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 use the same methodology that we use to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this proposed rule (which is available via the internet on the CMS website [1]) and are discussed in more detail in section II.A.1.b of this proposed rule,

For CY 2023, we are able to identify approximately 0.95 million ''single session'' claims out of an estimated 2.0 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 47.5 percent of all eligible claims, to calculate the proposed CY 2023 geometric mean costs for the multiple imaging composite APCs. Table 2 of this 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 2023.

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[1] CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS–1772–P); Notice of Proposed Rulemaking. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

TABLE 2: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2023 APC 8004 (Ultrasound Composite)	**CY 2023 Approximate APC Geometric Mean Cost = $290.66**
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
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2023 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2023 Approximate APC Geometric Mean Cost = $218.54**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
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
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye

CY 2023 APC 8006 (CT and CTA with Contrast Composite)	CY 2023 Approximate APC Geometric Mean Cost = $424.16
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
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
70487	Ct maxillofacial 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
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* 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.	

Family 3 - MRI and MRA with and without Contrast	
CY 2023 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2023 Approximate APC Geometric Mean Cost = $509.37**
0609T	Mrs disc pain acquisj data
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
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
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
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2023 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2023 Approximate APC Geometric Mean Cost = $821.63**
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
70549	Mr angiograph neck w/o & 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
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.	

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3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

b. Proposal and Comment Solicitation on Packaged Items and Services

For CY 2023, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2023, we are not proposing any changes to the overall packaging policy previously discussed. We propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

While we are not proposing any changes to the overall packaging policy above, we are soliciting comments on potential modifications to our packaging policy, as described in section XIII.E.5 of this proposed rule. Specifically, we are seeking comments and data regarding whether to expand the current ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies to the HOPD setting. Details on the current ASC policy can be found in XIII.E.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2022 OPPS/ASC final rule with comment period (85 FR 63497 through 63498), we applied this policy and calculated the relative payment weights for each APC for CY 2022 that were shown in Addenda A and B of the CY 2022 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of the CY 2022 OPPS/ASC final rule with comment period. For CY 2023, as we did for CY 2022, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2023 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 70372). For CY 2023, as we did for CY 2022, we proposed 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 2023, as we did for CY 2022, we

proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61365 through 61369), we discuss our policy, implemented beginning on January 1, 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based departments (PBDs) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically, under this policy, there is no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

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 2023 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2022 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2023 unscaled relative payment weights.

For CY 2022, we multiplied the CY 2022 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2021 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 2023, we propose to apply the same process using the estimated CY 2023 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2022 estimated aggregate weight by the unscaled CY 2023 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 website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the link labeled ''CY 2023 OPPS/ASC Notice of Proposed Rulemaking'', which can be found under the heading ''Hospital Outpatient Prospective Payment System Rulemaking'' and open the claims accounting document link at the bottom of the page, which is labeled ''2023 NPRM OPPS Claims Accounting (PDF)''.

We propose to compare the estimated unscaled relative payment weights in CY 2023 to the estimated total relative payment weights in CY 2022 using CY 2021 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2023 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2023 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4152 to ensure that the proposed CY 2023 relative payment weights are scaled to be budget neutral. The proposed CY 2023 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) are 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 specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2 of this proposed rule) is included in the budget neutrality calculations for the CY 2023 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 rate 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 rate 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 2023 IPPS/LTCH PPS proposed rule (87 FR 28402), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2021 forecast of the FY 2023 market basket increase, the proposed FY 2023 IPPS market basket update was 3.1 percent. We note that under our regular process for the CY 2023 OPPS/ASC final rule, we will use the market basket update for the FY 2023 IPPS/LTCH PPS final rule, which would be based on IHS Global, Inc.'s second quarter 2022 forecast of the FY 2023 market basket increase. If that forecast is higher than the market basket used for this proposed rule, the CY 2023 OPPS/ASC final rule OPD rate increase factor will reflect that higher market basket estimate.

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 2023 IPPS/LTCH PPS proposed rule (87 FR 28402), the proposed MFP adjustment for FY 2023 was 0.4 percentage point.

Therefore, we propose that the MFP adjustment for the CY 2023 OPPS will be 0.4 percentage point. We also propose that if more recent data become subsequently available after the publication of the CY 2023 OPPS/ASC proposed rule (for example, a more

recent estimate of the market basket increase and/or the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2023 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 2023 OPPS/ASC final rule.

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 propose for CY 2023 an OPD fee schedule increase factor of 2.7 percent for the CY 2023 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.1 percent, less the proposed 0.4 percentage point MFP adjustment).

We propose that hospitals that fail to meet the Hospital OQR Program reporting requirements would be 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 XIV of this proposed rule.

To set the OPPS conversion factor for 2023, we propose to increase the CY 2022 conversion factor of $84.177 by 2.7 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2023 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 1.0010 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2023 IPPS wage indexes to those payments using the FY 2022 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further propose to calculate an additional budget neutrality factor of 0.9995 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis.

For the CY 2023 OPPS, we propose 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 is 1.0000.

We propose 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 propose to calculate a CY 2023 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2023 payments under section 1833(t) of the Act, including the proposed CY 2023 cancer hospital payment adjustment, to estimated CY 2023 total payments using the CY 2022 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2023 estimated payments applying the proposed CY 2023 cancer hospital payment adjustment were the same as estimated payments applying the CY 2022 final cancer hospital payment adjustment. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C), as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), 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 applied as stated in section II.F. of this proposed rule.

We estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2023 would equal approximately $772.0 million, which represents 0.90 percent of total projected CY 2023 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 1.24 percent estimate of pass-through spending for CY 2022 and the 0.90 percent estimate of proposed pass-through spending for CY 2023, resulting in a proposed increase to the conversion factor for CY 2023 of 0.34 percent.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2023. We estimate for the proposed rule that outlier payments would be approximately 1.29 percent of total OPPS payments in CY 2022; the 1.00 percent for proposed outlier payments in CY 2023 would constitute a 0.29 percent decrease in payment in CY 2023 relative to CY 2022.

We also propose to make an OPPS budget neutrality adjustment of 0.01 percent of the OPPS for the estimated spending of $8.3 million associated with the proposed payment adjustment under the CY 2023 OPPS for domestic NIOSH-approved surgical N95 respirators, as discussed in section X.H of this proposed rule.

For CY 2023, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.7 percent (that is, the proposed OPD fee schedule increase factor of 2.7 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2023 of $85.093 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.692 in the conversion factor relative to hospitals that met the requirements).

In summary, for 2023, we propose to use a reduced conversion factor of $85.093 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.692 in the conversion factor relative to hospitals that met the requirements).

For 2023, we propose to use a conversion factor of $86.785 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 2.7 percent for CY 2023, the required proposed wage index budget neutrality adjustment of approximately 1.0010, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9995, the proposed cancer hospital payment adjustment of 1.0000, the proposed adjustment to account for the 0.01 percentage point of OPPS spending associated with the payment adjustment for domestic NIOSH-approved surgical N95 respirators, and the proposed adjustment of an increase of 0.34 percentage point of projected OPPS spending for the difference in pass-through spending, which that result in a proposed conversion factor for CY 2023 of $86.785.

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 OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2023 OPPS. 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 website), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2023 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For 2023, we propose 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. 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 FY 2011 through FY 2022 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; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; and for FY 2022, 86 FR 45178.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2023 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. We refer readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) for a detailed discussion of all proposed changes to the FY 2023 IPPS wage indexes. We note in particular that in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28377 through 28380), we proposed a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, we proposed to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we proposed that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We stated that we believe this policy would increase the predictability of IPPS payments for hospitals and mitigate instability and significant negative impacts to hospitals resulting from changes to the wage index. It would also eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside hospitals' control.

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 final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS 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. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html* (which, as of May 6, 2019, migrated to: *https://www.census.gov/programs-surveys/geography.html*). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal 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, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we

finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2023, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2023 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2023. Therefore, any policies and adjustments for the FY 2023 IPPS post-reclassified wage index, including, but not limited to, the 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY described above, would be reflected in the final CY 2023 OPPS wage index beginning on January 1, 2023. We refer readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) and the proposed FY 2023 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-proposed-rule-home-page*. With regard to budget neutrality for the CY 2023 OPPS wage index, we refer readers to section II.B of this proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We propose to continue this policy for CY 2023 and are including below a brief summary of the major proposed FY 2023 IPPS wage index policies and adjustments that we propose to apply to these hospitals under the OPPS for CY 2023. We refer readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) for a detailed discussion of the proposed changes to the FY 2023 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index 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 2023, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, we propose that the wage index that would apply for CY 2023 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5 percent cap on wage index decreases that we may finalize for the FY 2023 IPPS wage index as discussed previously.

For CMHCs, for CY 2023, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we propose that the wage index that would apply to a CMHC for CY 2023 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include the 5 percent cap on wage index decreases that we may finalize for the FY 2023 IPPS wage index as discussed above. Also, we propose that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

Table 4A associated with the FY 2023 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) identifies counties eligible for the out-migration adjustment. Table 2 associated with the FY 2023 IPPS/LTCH PPS final rule (available for download via the website above) identifies IPPS hospitals that receive the out-migration adjustment for FY 2023. We are including the outmigration adjustment information from Table 2 associated with the FY 2023 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 outmigration adjustment under this proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index*. At this link, readers will find a link to the proposed FY 2023 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use 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 outpatient payments (TOPs) under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes 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. We also use the statewide average default CCRs to determine payments for hospitals whose 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).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2023 OPPS proposed rule Claims Accounting document that is posted on our website. Due to concerns with cost report data as a result of the COVID–19 PHE, we propose to calculate the default ratios for CY 2023 using the June 2020 HCRIS cost reports, consistent with the broader proposal regarding CY 2023 OPPS ratesetting discussed in section X of this proposed rule.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the

upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; click on the link on the left of the page titled ''Hospital Outpatient Regulations and Notices'' and then select the relevant regulation to download the statewide CCRs and upper limit in the Downloads section of the web page.

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 2023

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, 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 our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also 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 2022.

For CY 2023, we propose to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2023

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), the Congress added section 1833(t)(7), ''Transitional Adjustment to Limit Decline in Payment,'' to the Act, which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as ''held harmless'' and their payments are often referred to as ''hold harmless'' payments).

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 § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the

calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 3 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2022.

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TABLE 3: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT PAYMENT-TO-COST RATIOS (PCRs), CY 2012 THROUGH CY 2022

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89

2. Proposed Policy for CY 2023

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 § 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.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act. We do not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2023.

Under our established policy, to calculate the proposed CY 2023 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2023 OPPS which, in most cases, would be the most recently available hospital cost reports. However, as discussed in section II.A.1.c and X.C of this proposed rule, we propose to use cost report data from the June 2020 HCRIS data set, which does not contain cost reports from CY 2020, given our concerns with CY 2020 cost report data as a result of the COVID–19 PHE. We believe a target PCR based on the most recently available cost reports may provide a less accurate estimation of cancer hospital PCRs and non-cancer hospital PCRs than the data used for the CY 2022 rulemaking cycle, which pre-dated the COVID–19 PHE. Therefore, for CY 2023, we propose to continue to use the same target PCR we used for CY 2021 and CY 2022 of 0.89. This proposed CY 2023 target PCR of 0.89 includes the 1.0-percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2023. For a description of the CY 2021 target PCR calculation, on which the proposed CY 2023 target PCR is based, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (84 FR 85912 through 85914).

Table 4 shows the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2023, due to the cancer hospital payment adjustment policy. The cost reporting periods for all cancer hospitals in Table 4 overlaps with CY 2020 and the costs and payments associated with each cancer hospital may be impacted by the effects of the COVID–19 PHE. Therefore, the estimates in Table 4 are likely to be less accurate than in other years and may overstate the percentage increase in cancer hospital payments for CY 2023. The actual, final amount of the CY 2023 cancer hospital payment adjustment for each cancer hospital would be determined at cost report settlement and would depend on each hospital's CY 2023 payments and costs from the settled CY 2023 cost report. 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 4: Estimated CY 2023 Hospital-Specific Payment Adjustment For Cancer Hospitals To Be Provided At Cost Report Settlement

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2023 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	45.5%
050660	USC Norris Cancer Hospital	31.7%
100079	Sylvester Comprehensive Cancer Center	24.1%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.1%
220162	Dana-Farber Cancer Institute	42.7%
330154	Memorial Sloan-Kettering Cancer Center	69.2%
330354	Roswell Park Cancer Institute	15.2%
360242	James Cancer Hospital & Solove Research Institute	12.9%
390196	Fox Chase Cancer Center	23.5%
450076	M.D. Anderson Cancer Center	49.4%
500138	Seattle Cancer Care Alliance	46.1%

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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 dollar amount). In CY 2022, 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 $6,175 (the fixed-dollar amount threshold) (86 FR 63508 through 63510). If the hospital's cost of furnishing 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 hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2021 OPPS payments, using CY 2021 claims available for this CY 2023 OPPS/ASC proposed rule, is approximately 1.0 percent. Therefore, for CY 2021, we estimated that we paid the outlier target of 1.0 percent of total aggregated OPPS payments. Using an updated claims dataset for this proposed rule, we estimate that we paid approximately 1.01 percent of the total aggregate OPPS payments in outliers for CY 2021.

For this proposed rule, using CY 2021 claims data and CY 2022 payment rates, we estimate that the aggregate outlier payments for CY 2022 would be approximately 1.07 percent of the total CY 2022 OPPS payments. We provide estimated CY 2023 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 website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Outlier Calculation for CY 2023

For CY 2023, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. We propose to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds

3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C of this proposed rule.

To ensure that the estimated CY 2023 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we propose 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 $8,350.

We calculate the proposed fixed-dollar threshold of $8,350 using the standard methodology most recently used for CY 2022 (86 FR 63508 through 63510). For purposes of estimating outlier payments for CY 2023, we use the hospital-specific overall ancillary CCRs available in the April 2022 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we generally use to model each OPPS update lag by 2 years.

In order to estimate the CY 2023 hospital outlier payments, we inflate the charges on the CY 2021 claims using the same proposed charge inflation factor of 1.13218 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28667). We used an inflation factor of 1.06404 to estimate CY 2022 charges from the CY 2021 charges reported on CY 2021 claims before applying CY 2022 CCRs to estimate the percent of outliers paid in CY 2022. The proposed methodology for determining these charge inflation factors, as well as the solicitation of comments on an alternative approach, is discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28667 through 28678). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR adjustment factor that we proposed to apply for the FY 2023 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2023 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2023, we propose to apply an adjustment factor of 0.974495 to the CCRs that were in the April 2022 OPSF to trend them forward from CY 2022 to CY 2023. The methodology for calculating the proposed CCR adjustment factor, as well as the solicitation of comments on an alternative approach, is discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28668). We note that we propose to use the April 2022 OPSF for purposes of estimating costs for the OPPS outlier threshold calculation whereas in section X of this proposed rule we discussed using June 2020 HCRIS data extract for modeling hospital outpatient costs in construction of our CY 2023 OPPS relative weights. For modeling estimated outlier payments, since the April 2022 OPSF contains cost data primarily from CY 2021 and CY 2022 and is the basis for current CY 2022 OPPS outlier payments, we believe the April 2022 OPSF provides a more updated and accurate data source for determining the CCRs that will be applied to CY 2023 hospital outpatient claims. Therefore, we believe the April 2022 OPSF is a more accurate data source for determining the fixed-dollar threshold to ensure that the estimated CY 2023 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS.

To model hospital outlier payments for this CY proposed rule, we apply the overall CCRs from the April 2022 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.974495 to approximate CY 2023 CCRs) to charges on CY 2021 claims that were adjusted (using the proposed charge inflation factor of 1.13218 to approximate CY 2023 charges). We simulated aggregated CY 2021 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 2023 OPPS payments. We estimated that a proposed fixed-dollar threshold of $8,350, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we propose 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 would 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 propose to continue the policy that we implemented in CY 2010 that the hospitals' costs would 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 XIV 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 OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2023 proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B of this proposed rule and the relative payment weight described in section II.A. of this proposed rule. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via

the internet on the CMS website) is calculated by multiplying the proposed CY 2023 scaled weight for the APC by the CY 2023 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 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 XIV. of this proposed rule.

We demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''Q4'', ''R'', ''S'', ''T'', ''U'', or ''V'' (as defined in Addendum D1 to this proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9805 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2023 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS/ASC final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 *$ (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2023 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We propose to continue to apply for the CY 2023 OPPS wage index any adjustments for the FY 2023 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we are applying for the CY 2023 OPPS, we refer readers to section II.C of this proposed rule.

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 website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2023 IPPS wage index, which are listed in Table 3 associated with the FY 2023 IPPS proposed rule and available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* (Click on the link on the left side of the screen titled ''FY 2023 IPPS Proposed Rule Home Page'' and select ''FY 2023 Proposed Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

$X_a = .60 *$ (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

$Y = .40 *$ (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an

SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The CY 2023 full national unadjusted payment rate for APC 5071 is $659.86. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $646.99. This proposed reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

The FY 2023 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2023 wage index policies, is 1.3296. The labor-related portion of the proposed full national unadjusted payment is approximately $526.42 (.60 * $659.86 * 1.3296). The labor-related portion of the proposed reduced national adjusted payment is approximately $516.14 (.60 * $646.99 * 1.3296). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $263.94 (.40 * $659.86). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately $258.80 (.40 * $646.99). The sum of the labor-related and nonlabor-related portions of the proposed full national unadjusted payment is approximately $790.36 ($526.42 + $263.94). The sum of the portions of the proposed reduced national adjusted payment is approximately $774.94 ($516.14 + $258.80).

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 CYs 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 (including items such as drugs and biologicals) 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. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011 we refer readers to section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B, ''Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests'' of the CY 2022 OPPS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through 2026 (and the corresponding reduction in coinsurance) is 85 percent (with beneficiary coinsurance equal to 15 percent).

2. Proposed OPPS Copayment Policy

For CY 2023, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2023 are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E of this proposed rule, for CY 2023, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves

beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. 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, $131.98 is approximately 20 percent of the full national unadjusted payment rate of $659.86. 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 website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this 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 0.9805.

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2023 are shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). 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 2023 OPD increase factor discussed in section II.B of this proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, MAAA, and PLAA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products,

supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPPS payment system. Specifically, we recognize the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new 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 more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively 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. In section XI of this proposed rule, specifically, the ''Proposed CY 2023 Payment Status and Comment Indicators'' section, we discuss the various status indicators used under the OPPS. We also provide a complete list of the proposed status indicators and their definitions in Addendum D1 to this proposed rule.

1. April 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2022 update, 48 new HCPCS codes were established and made effective on April 1, 2022. Through the April 2022 OPPS quarterly update CR (Transmittal 11305, Change Request 12666, dated March 24, 2022), we recognized several new HCPCS codes for separate payment under the OPPS. In this proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed in Table 5 (New HCPCS Codes Effective April 1, 2022). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. We note that in prior years we included the proposed OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 5. Therefore, readers are advised to refer to the OPPS Addendum B for the OPPS status indicator, APC assignment, and payment rates for all codes reportable under the hospital OPPS. The new codes effective April 1, 2022 are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed status indicators and definitions used under the OPPS can be found in Addendum D1 to this proposed rule, while the complete list of proposed comment indicators and definitions can be found in Addendum D2. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

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TABLE 5: NEW HCPCS CODES EFFECTIVE APRIL 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
A2011	Supra sdrm, per square centimeter
A2012	Suprathel, per square centimeter
A2013	Innovamatrix fs, per square centimeter
A4100	Skin substitute, fda cleared as a device, not otherwise specified
A4238	Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9291	Prescription digital behavioral therapy, fda cleared, per course of treatment
C9090	Injection, plasminogen, human-tvmh, 1 mg
C9091	Injection, sirolimus protein-bound particles, 1 mg
C9092	Injection, triamcinolone acetonide, suprachoroidal, 1 mg
C9093	Injection, ranibizumab, via intravitreal implant, 0.1 mg
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study
C9783	Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catherization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved Investigational Device Exemption (IDE) study
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0491	Injection, anifrolumab-fnia, 1 mg
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)
J9071	Injection, cyclophosphamide, (auromedics), 5 mg
J9273	Injection, tisotumab vedotin-tftv, 1 mg
J9359	Injection, loncastuximab tesirine-lpyl, 0.1 mg
K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application

CY 2022 HCPCS Code	CY 2022 Long Descriptor
K1029	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only
K1031	Non-pneumatic compression controller without calibrated gradient pressure
K1032	Non-pneumatic sequential compression garment, full leg
K1033	Non-pneumatic sequential compression garment, half leg
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	Amniobind, per square centimeter
Q4256	Mlg-complete, per square centimeter
Q4257	Relese, per square centimeter
Q4258	Enverse, per square centimeter
Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg
V2525	Contact lens, hydrophilic, dual focus, per lens
0306U	Oncology (minimal residual disease [mrd]), next-generation targeted sequencing analysis, cell-free dna, initial (baseline) assessment to determine a patient specific panel for future comparisons to evaluate for mrd
0307U	Oncology (minimal residual disease [mrd]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free dna, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for mrd
0308U	Cardiology (coronary artery disease [cad]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [kim-1]), plasma, algorithm reported as a risk score for obstructive cad
0309U	Cardiology (cardiovascular disease), analysis of 4 proteins (nt-probnp, osteopontin, tissue inhibitor of metalloproteinase-1 [timp-1], and kidney injury molecule-1 [kim-1]), plasma, algorithm reported as a risk score for major adverse cardiac event
0310U	Pediatrics (vasculitis, kawasaki disease [kd]), analysis of 3 biomarkers (nt-probnp, c-reactive protein, and t-uptake), plasma, algorithm reported as a risk score for kd
0311U	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)–based antimicrobial susceptibility for each organisms identified
0312U	Autoimmune diseases (eg, systemic lupus erythematosus [sle]), analysis of 8 igg autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (elisa), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic sle-likelihood assessment

CY 2022 HCPCS Code	CY 2022 Long Descriptor
0313U	Oncology (pancreas), dna and mrna next-generation sequencing analysis of 74 genes and analysis of cea (ceacam5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (ie, negative, low probability of neoplasia or positive, high probability of neoplasia)
0314U	Oncology (cutaneous melanoma), mrna gene expression profiling by rt-pcr of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (ffpe) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)
0315U	Oncology (cutaneous squamous cell carcinoma), mrna gene expression profiling by rt-pcr of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (ffpe) tissue, algorithm reported as a categorical risk result (ie, class 1, class 2a, class 2b)
0316U	Borrelia burgdorferi (Lyme disease), ospa protein evaluation, urine
0317U	Oncology (lung cancer), four-probe fish (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer
0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood
0319U	Nephrology (renal transplant), rna expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection
0320U	Nephrology (renal transplant), rna expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection
0321U	Infectious agent detection by nucleic acid (dna or rna), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique
0322U	Neurology (autism spectrum disorder [asd]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (lc-ms/ms), plasma, results reported as negative or positive for risk of metabolic subtypes associated with asd

2. July 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the July 2022 update, 63 new codes were established and made effective July 1, 2022. Through the July 2022 OPPS quarterly update CR (Transmittal 11457, Change Request 12761, dated June 15, 2022), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In this CY 2023 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed in Table 6 (New HCPCS Codes Effective July 1, 2022). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. We note that in prior years we included the proposed OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 6. Therefore, readers are advised to refer to the OPPS Addendum B for the OPPS status indicator, APC assignment, and payment rates for all codes reportable under the hospital OPPS. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

TABLE 6: NEW HCPCS CODES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie
C9094	Inj, sutimlimab-jome, 10 mg
C9095	Inj, tebentafusp-tebn, 1 mcg
C9096	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram
C9097	Inj, faricimab-svoa, 0.1 mg
C9098	ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
D1708	Pfizer-BioNTech Covid-19 vaccine administration – third dose
D1709	Pfizer-BioNTech Covid-19 vaccine administration – booster dose
D1710	Moderna Covid-19 vaccine administration – third dose
D1711	Moderna Covid-19 vaccine administration – booster dose
D1712	Janssen Covid-19 vaccine administration - booster dose
D1713	Pfizer-BioNTech Covid-19 vaccine administration tris-sucrose pediatric – first dose
D1714	Pfizer-BioNTech Covid-19 vaccine administration tris-sucrose pediatric – second dose
G0308	Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training
G0309	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation
J0739	Injection, cabotegravir, 1 mg
J1306	Injection, inclisiran, 1 mg
J1551	Injection, immune globulin (cutaquig), 100 mg
J2356	Injection, tezepelumab-ekko, 1 mg
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2998	Injection, plasminogen, human-tvmh, 1 mg
J3299	Injection, triamcinolone acetonide (xipere), 1 mg
J9331	Injection, sirolimus protein-bound particles, 1 mg

CY 2022 HCPCS Code	CY 2022 Long Descriptor
J9332	Injection, efgartigimod alfa-fcab, 2mg
K1034	Provision of covid-19 test, nonprescription self-administered and self-collected use, fda approved, authorized or cleared, one test count
Q4259	Celera dual layer or celera dual membrane, per square centimeter
Q4260	Signature apatch, per square centimeter
Q4261	Tag, per square centimeter
90584	Dengue vaccine, quadrivalent, live, 2 dose schedule, for subcutaneous use
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score
0717T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing and concentration of ADRCs
0718T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy

CY 2022 HCPCS Code	CY 2022 Long Descriptor
	(eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)
0725T	Vestibular device implantation, unilateral
0726T	Removal of implanted vestibular device, unilateral
0727T	Removal and replacement of implanted vestibular device, unilateral
0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming
0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming
0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
0731T	Augmentative AI-based facial phenotype analysis with report
0732T	Immunotherapy administration with electroporation, intramuscular
0733T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days
0734T	Remote body and limb kinematic measurement-based therapy ordered by a physician or other qualified health care professional; treatment management services by a physician or other qualified health care professional, per calendar month
0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)
0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter
0737T	Xenograft implantation into the articular surface
0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi
0324U	Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug
0325U	Oncology (ovarian), spheroid cell culture, poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), tumor response prediction for each drug
0326U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
0327U	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed

CY 2022 HCPCS Code	CY 2022 Long Descriptor
0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service
0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
0331U	Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alternations

3. October 2022 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2023 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2022, in the CY 2023 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2024 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2022 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2023, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the CY 2023 OPPS/ASC final rule with comment period to those new HCPCS codes that will be effective October 1, 2022, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2023 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2024 OPPS/ASC final rule with comment period.

4. January 2023 HCPCS Codes

a. New Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2023 OPPS/ASC Final Rule With Comment Period

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2023, in the CY 2023 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2024 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2023, we propose to include in Addendum B to the CY 2023 OPPS/ASC final rule with comment period the new Level II HCPCS codes effective January 1, 2023, that would be incorporated in the January 2023 OPPS quarterly update CR. Specifically, for CY 2023, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the CY 2023 OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 1, 2023, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2023 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2024 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if

we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of 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), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2023 OPPS update, we received the CPT codes that will be effective January 1, 2023 from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note 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 the long descriptors for the new and revised CY 2023 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) 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 2023 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers will be included in the CY 2023 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2023 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2023. Because the CPT codes listed in Addendum B appear with short descriptors only, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2023 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignments for these codes can be found in Addendum B to this proposed rule. In addition, the complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

Finally, in Table 7 (Comment and Finalization Timeframes for New and Revised OPPS-Related HCPCS Codes) below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

TABLE 7: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPS-RELATED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2022	HCPCS (CPT and Level II codes)	April 1, 2022	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
July 2022	HCPCS (CPT and Level II codes)	July 1, 2022	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
October 2022	HCPCS (CPT and Level II codes)	October 1, 2022	CY 2023 OPPS/ASC final rule with comment period	CY 2024 OPPS/ASC final rule with comment period
January 2023	CPT Codes	January 1, 2023	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2023	CY 2023 OPPS/ASC final rule with comment period	CY 2024 OPPS/ASC final rule with comment period

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric 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 regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3 of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2023, we propose that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review

(and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the CY 2023 OPPS update will be discussed in the relevant specific sections throughout the CY 2023 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for 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 2023, we propose 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 2023 OPPS update, we identified the APCs with violations of the 2 times rule and we propose changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we propose a 2 times rule exception) 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 proposed rule. Rather, it is published and made available via the internet on the CMS website 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 in the APCs for which we are not proposing a 2 times rule exception, we propose 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 2023 included in this proposed rule are related to changes in costs of services that were observed in the CY 2021 claims data available for CY 2023 ratesetting. Addendum B to this CY 2023 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2022 OPPS Addendum B Update (available via the internet on the CMS website 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 propose to make for CY 2023, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether any of the APCs would qualify for an exception. 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 final rule (65 FR 18457 through 18458).

Based on the CY 2021 claims data available for this proposed rule, we found 23 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2023 and found that all of the 23 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2021 claims data available for this proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 8 below. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 8 of this proposed rule lists the 23 APCs for which we propose to make an exception under the 2 times rule for CY 2023 based on the criteria cited above and claims data submitted between January 1, 2021 and December 31, 2021 and processed on or before December 31, 2021, and CCRs, if available. The proposed 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 website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

TABLE 8: PROPOSED CY 2023 APC EXCEPTIONS TO THE 2 TIMES RULE

Proposed CY 2023 APC	Proposed CY 2023 APC Title
5012	Clinic Visits and Related Services
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
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
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

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C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS 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.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: 1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; 2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for a pass-through payment); and 3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment* on the CMS website and then follow the instructions to access the MEARIS™ system for OPPS New Technology APC applications.

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.

For CY 2022, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) to the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. 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.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and 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 technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

We note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2023, we include the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this proposed rule (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be significant contributors to the APC ratesetting calculations and, therefore, are not included in the assessment of the 2 times rule. As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892), we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a service to a New Technology APC allows us to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we adopted a policy in the CY 2019 OPPS/ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893).

For purposes of this adjustment, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believed that it was appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has an annual claims volume of fewer than 100 claims (83 FR 58893). Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we also stated that using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of ''outlier'' claims; that is, claims with either a very low or very high payment rate as compared to the average claim, which would have a substantial impact

on any statistical methodology used to estimate the most appropriate payment rate for a service. Also, having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services helps to create a more stable payment rate.

In the CY 2019 OPPS/ASC final rule (83 FR 58893), we implemented a policy that we would seek public comments on which statistical methodology should be used to determine the payment rate for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we explained that we would use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other interested parties, to determine the most appropriate payment rate. Once we identified the most appropriate payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

In the CY 2022 OPPS/ASC final rule with comment period, we adopted a policy to continue to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using up to four years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC (86 FR 63529). However, we replaced our specific low-volume New Technology APC policy with the universal low volume APC policy that we adopted beginning in CY 2022. Our universal low volume APC policy is similar to our past New Technology APC low volume policy except that the universal low volume APC policy applies to clinical APCs and brachytherapy APCs as well as low volume procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to assign a procedure with fewer than 100 claims per year to an appropriate New Technology APC. For this proposed rule, we propose to designate three procedures assigned to New Technology APCs as low volume procedures and use the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to assign such procedures to the appropriate New Technology APCs.

3. Procedures Assigned to New Technology APC Groups for CY 2023

As we described in the CY 2002 OPPS final rule (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 2023, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. 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 FDA in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. For information on the utilization and payment history of the Argus® II procedure and the Argus® II device through CY 2022, please refer to the CY 2022 OPPS final rule (86 FR 63529 through 63530).

Early in 2022, we learned that the manufacturer of the Argus® II device discontinued manufacturing the device in 2020. We also contacted the consultant who represented the manufacturer in presentations with CMS, and he confirmed that the Argus® II device is no longer being implanted. A review of OPPS claims data found that there were no claims billed for CPT code 0100T in either CY 2020 or CY 2021. Based on this information, we have determined that the Argus® II device is no longer available in the marketplace and that outpatient hospital providers are no longer performing the Argus® II implantation procedure. Therefore, we propose to make changes to the OPPS status indicators for HCPCS and CPT codes that are related to the Argus® II device and the Argus® II implantation procedure to indicate that Medicare payment is no longer available for the device and the implementation procedure as the Argus® II device is no longer on the market and therefore, is not being implanted. These coding changes would mean that providers could no longer receive payment for performing the Argus® II device or the device implantation procedure. These changes are described in Table 9.

TABLE 9: CY 2023 PROPOSED OPPS STATUS INDICATOR AND APC ASSIGNMENTS FOR THE ARGUS® II DEVICE AND THE ARGUS® II IMPLANTATION PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy	T	1908	E2	N/A
C1841	Retinal prosthesis, includes all internal and external components	N	N/A	D	N/A

b. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1562)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3,001–$3,500)). This code may be used to describe the administration of CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology—Level 24 ($3,001–$3,500)) for HCPCS code C9770 (86 FR 63531 through 63532).

CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[2] This therapy is administered through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.''

Interested parties, including the manufacturer of Luxturna®, recommended HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[3] However, the manufacturer previously contended the administration was not accurately described by any existing codes as HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself.

CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed that this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that HCPCS code 67036 represents a clinically similar procedure and process that approximates similar resource utilization to C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C–APC to which HCPCS code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for HCPCS code 67036. The placeholder code C97X1 was replaced by C9770. For CY 2021, we finalized our proposal to create C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code to APC 1561 (New Technology—Level 24 ($3,001–$3,500)) using the geometric mean cost of HCPCS code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology—Level 24 ($3,001–$3,500)) using the geometric mean cost of HCPCS code 67036.

For CY 2023, there are 11 single claims available for ratesetting for HCPCS code C9770. Because this is the first year we have claims data for HCPCS code C9770, we propose to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of HCPCS code 67036. Given the low number of claims for this procedure, we propose to designate HCPCS C9770 as a low volume procedure under our universal low volume APC policy and use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning C9770 to a New Technology APC.

Using CY 2021 claims, which are the only claims available in our 4-year look back period, we found the geometric mean cost for the service to be

[2] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download.*

[3] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf.*

approximately $3,326, the arithmetic mean cost to be approximately $3,466, and the median cost to be approximately $3,775. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we propose to assign HCPCS code C9770 to APC 1562 for CY 2023.

Please refer to Table 10 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9770 for CY 2023. The proposed CY 2023 payment rates can be found in Addendum B to this proposed rule.

TABLE 10: FINAL CY 2022 & PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9770

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561	T	1562

c. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3–D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500.

In claims data available for CY 2019 for the CY 2021 OPPS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $2,693, the arithmetic mean cost to be approximately $3,086, and the median cost to be approximately $3,708. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

In CY 2022, we used again the claims data from CY 2019 for HCPCS code C9751. Since the claims data was unchanged from when it was used in CY 2021, the values for the geometric mean cost ($2,693), the arithmetic mean cost ($3,086), and the median cost ($3,708) for the service described by HCPCS code C9751 remained the same. The highest cost metric using these methodologies was again the median and within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we continued to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501– $4,000)), with a payment rate of $3,750.50 for CY 2022.

There were no claims reported in CY 2020 or CY 2021 for HCPCS code C9751. Thus, for CY 2023, the only available claims for HCPCS code C9751 continue to be from CY 2019, and the reported claims are the same claims used to calculate the payment rate for the service in the CY 2021 and CY 2022 OPPS/ASC final rules with comment period. Therefore, given the low number of claims for this procedure, we propose to designate this procedure as low volume under our universal low volume policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the procedure to the appropriate New Technology APCs. Because our proposal uses the same claims as we used for CY 2021 and CY 2022, we found the same values for the geometric mean cost, arithmetic mean cost, and the median cost for CY 2023. Once again, the median ($3,708) was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology continues to fall within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we propose to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501–$4,000)), with a proposed payment rate of $3,750.50 for CY 2023. Details regarding HCPCS code C9751 are included in Table 11.

TABLE 11: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1562	T	1562

d. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1522 and 1523)

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50. We did not receive any claims data for these services for either of the CY 2021 or CY 2022 OPPS proposed or final rules. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50 in CY 2021 and CY 2022. Likewise, we continued to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50.

For CY 2023, we propose to use CY 2021 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. CPT code 78431 had over 18,000 single frequency claims in CY 2021, which are used to calculate estimated costs for individual services. The geometric mean for CPT code 78431 was approximately $2,509, which is an amount that is above the cost band for APC 1522 (New Technology—Level 22 ($2,001–$2,500)), where the procedure is currently assigned. We propose, for CY 2023, that CPT code 78431 be reassigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50. Please refer to Table 12 for the proposed New Technology APC and status indicator assignments for CPT code 78431.

There were only 5 single frequency claims in CY 2021 for CPT code 78432. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Although we use up to four years of claims data to calculate the appropriate New Technology APC assignment for low volume procedures, for CPT code 78432, the only available claims data are from CY 2021. Our analysis of the data found the geometric mean cost of the service is approximately $1,747, the arithmetic mean cost of the service is approximately $1,899, and the median cost of the service is approximately $1,481. The arithmetic mean was the statistical methodology that estimated the highest cost for the service. Therefore, we propose, for CY 2023, to assign CPT code 78432 to APC 1520 (New Technology—Level 20 ($1,801–$1,900)) with a payment rate of $1,850.50. Please refer to Table 12 for the proposed on New Technology APC and status indicator assignments for CPT code 78432.

There were 954 single frequency claims reporting CPT code 78433 in CY 2021. The geometric mean for CPT code 78433 was approximately $1,999, which is an amount that is below the cost band for APC 1523 (New Technology—Level 23 ($2,501–$3,000)), where the procedure is currently assigned. We propose, for CY 2023, that CPT code 78433 be reassigned to APC 1521 (New Technology—Level 21 ($1,901–$2,000)) with a payment rate of $1,950.50. Please refer to Table 12 for the proposed New Technology APC and status indicator assignments for CPT code 78433.

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TABLE 12: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed OPPS CY 2023 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1523
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	S	1523	S	1520
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1521

e. V-Wave Medical Interatrial Shunt Procedure (APC 1590)

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they had received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 ($10,001–$15,000)).

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85946), we stated that we believe similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (HCPCS code C9760), except that payment for HCPCS codes C9758 and C9760 differs based on how often the interatrial shunt is implanted when

each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed, whereas an interatrial shunt is implanted every time HCPCS code C9760 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590, which reflects the cost of having surgery every time and receiving the interatrial shunt one-half of the time the procedure is performed.

For CY 2022, we used the same claims data from CY 2019 that we did for CY 2021 OPPS final rule. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022.

For CY 2023, there were no claims from CY 2021 billed with HCPCS code C9758. Because there are no claims reporting HCPCS code C9758, we propose to continue to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2023. The proposed New Technology APC and status indicator assignments for HCPCS codes C9758 are shown in Table 13.

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TABLE 13: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS SI	Proposed 2023 OPPS SI	Proposed 2023 OPPS SI
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590	T	1590

f. Corvia Medical Interatrial Shunt Procedure (APC 1592)

Corvia Medical is currently conducting its pivotal trial for its interatrial shunt procedure. The trial started in Quarter 1 of CY 2017 and continued through Quarter 3 of CY 2021.[4] On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule with comment period (85 FR 85947), we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. Unlike the V-Wave interatrial shunt, which is implanted half the time the associated interatrial shunt procedure described by HCPCS code C9758 is billed, the Corvia Medical interatrial shunt is implanted every time the associated interatrial

[4] *https://clinicaltrials.gov/ct2/show/NCT03088033?term=NCT03088033&rank=1.*

shunt procedure (HCPCS code C9760) is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New Technology APC 1592 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase ''or placebo control,'' from the descriptor. In CY 2022, we used the same claims data as was used in the CY 2021 OPPS final rule to determine the payment rate for HCPCS code C9760 because there were no claims for this service in CY 2019, the year used for ratesetting for CY 2022. Accordingly, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2022.

For CY 2023, we propose to use the claims data from CY 2021 to establish payment rates for services. However, there are no claims with HCPCS code C9760 in the CY 2021 claims data available for ratesetting. Therefore, we propose to continue to assign HCPCS code C9760 to New Technology APC 1592. The proposed New Technology APC and status indicator assignments for HCPCS code C9760 are shown in Table 14.

TABLE 14: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-RANDOMIZED, NON-BLINDED INTERATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed 2023 OPPS SI	Proposed 2023 OPPS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (eg, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	T	1592	T	1592

g. Supervised Visits for Esketamine Self-Administration (APCs 1512 and 1516)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two devices (for a 56 mg dose) or three devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for misuse of the product, Spravato is only available through a restricted distribution system under a REMS, patients must be monitored by a health care provider for at least two hours after receiving their Spravato dose, the prescriber and patient must both sign a Patient Enrollment Form, and the product must only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020.

HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes two hours of post-administration observation. HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine. HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50.

For CY 2023, we propose to use CY 2021 claims data to determine the payment rates for HCPCS codes G2082 and G2083. Therefore, for CY 2023, we propose to assign these two HCPCS codes to New Technology APCs based on the codes' geometric mean costs. Specifically, we propose to assign HCPCS code G2082 to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) based on its geometric mean cost of $995.47. We also propose to assign HCPCS code G2083 to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)) based on its geometric mean cost of $1,489.93.

Details about the proposed New Technology APC and status indicator assignments for these HCPCS codes are shown in Table 15. The proposed CY 2023 payment rates for these HCPCS codes can be found in Addendum B to this proposed rule.

TABLE 15: FINAL CY 2022 & PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1508	S	1511
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1511	S	1516

h. DARI Motion Procedure (APC 1505)

CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) was effective January 1, 2022. The technology consists of eight cameras that surround a patient. The cameras send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the need for special clothing, markers, or devices attached to the patient's clothing or skin. The technology is intended to guide health care providers on pre- and post-operative surgical intervention and on the best course of physical therapy and rehabilitation for patients. In CY 2022, we assigned CPT code 0693T to New Technology APC 1505 (New Technology—Level 5 ($301–$400)), for CY 2022.

This service became effective in the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data. Accordingly, for CY 2023 we propose to continue assigning CPT code 0693T to New Technology APC 1505. The proposed New Technology APC and status indicator assignments for CPT code 0693T are found in Table 16.

TABLE 16: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505	S	1505

i. Histotripsy Service (APC 1575)

CPT code 0686T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was effective July 1, 2021. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors. We note that the device that is used in the histotripsy procedure is currently under a Category A IDE clinical study (NCT04573881). The clinical trial is a non-randomized, prospective trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.[5] We note that devices from Category A IDE studies are excluded from Medicare payment. Therefore, payment for CPT code 0686T reflects only the service that is performed each time it is reported on a claim. For CY 2022, we assigned CPT code 0686T to New Technology APC 1575 (New Technology—Level 38 ($10,000–$15,000) with a payment rate of $12,500.

Since the service became effective in the OPPS in July 2021, there are no claims for this service in the CY 2021 OPPS claims data. Therefore, for CY 2023, we propose to continue assigning CPT code 0686T to New Technology APC 1575. The proposed New Technology APC and status indicator assignments for CPT code 0686T are found in Table17.

TABLE 17: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1575	S	1575

j. Liver Multiscan Service (APC 1511)

CPT code 0648T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.*, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure) during the same session; single organ) was effective July 1, 2021. LiverMultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. The SaaS receives MR images acquired from

[5] *ClinicalTrials.gov.* ''The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER).'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/study/NCT04573881.*

patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. The SaaS then sends the providers a quantitative metric report of the patient's liver fibrosis and inflammation. For CY 2022, we assigned CPT code 0648T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000) with a payment rate of $950.50.

Since HCPCS code 0648T became effective in the OPPS in July 2021, there has been only one claim from the CY 2021 claims data; but its payment rate appears to be an outlier based on the service invoice we received from the software developer. Accordingly, for CY 2023, we propose to continue assigning CPT code 0648T to New Technology APC 1511. The proposed New Technology APC and status indicator assignment for CPT code 0648T are found in Table 18.

TABLE 18: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; single organ	S	1511	S	1511

k. Minimally Invasive Glaucoma Surgery (MIGS) (APC 1526)

Prior to CY 2022, extracapsular cataract removal with insertion of intraocular lens was reported using CPT codes describing cataract removal alongside a CPT code for device insertion. Specifically, the procedure was described using CPT codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation) or 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation) and 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion).

For CY 2022, the AMA's CPT Editorial Panel created two new Category I CPT codes describing extracapsular cataract removal with insertion of intraocular lens prosthesis, specifically, CPT codes 66989 and 66991; deleted a Category III CPT code, specifically, CPT code 0191T, describing insertion of anterior segment aqueous drainage device; and created a new Category III CPT code, specifically, CPT code 0671T, describing interior segment aqueous drainage device without concomitant cataract removal.

For CY 2022, we finalized the assignment of CPT codes 66989 and 66991 to New Technology APC 1526 (New Technology—Level 26 ($4,001–$4,500)). We stated that we believed that

the change in coding for MIGS is significant in that it changes longstanding billing for the service from reporting two separate CPT codes to reporting a single bundled code. Without claims data, and given the magnitude of the coding change, we explained that we did not believe we had the necessary information on the costs associated with CPT codes 66989 and 66991 to assign them to a clinical APC at that time.

We note that for this proposed rule, the proposed payment rates are based on claims data submitted between January 1, 2021, and December 31, 2021, and processed on or before December 31, 2021, and CCRs, if available. Because CPT codes 66989 and 66991 were effective January 1, 2022, and we have no claims data for CY 2022, we propose to continue assigning CPT codes 66989 and 66991 to New Technology APC 1526 for CY 2023. The proposed New Technology APC and status indicator assignments for CPT codes 66989 and 66991 are found in Table 19.

Table 19: CY 2022 FINAL AND CY 2023 PROPOSED OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989 AND 66991

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed OPPS CY 2023 APC
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1526	S	1526
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1526	S	1526

l. Scalp Cooling (APC 1520)

CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) became effective on July 1, 2021 to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. According to Medicare's National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is classified as an incident to supply to a physician service, and would not be paid under the OPPS; however, interested parties have indicated that there are substantial resource costs of around $1,900 to $2,400 associated with calibration and fitting of the cap. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions. For CY 2022, we assigned CPT code 0662T to APC New Technology 1520 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1,850.50.

This service became effective in the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data. Accordingly, for CY 2023, we propose to continue assigning CPT code 0662T to New Technology APC 1520. The proposed New Technology APC and status indicator assignments for CPT code 0662T are found in Table 20.

TABLE 20: FINAL CY 2022 AND PROPOSED CY 2023 NEW TECHNOLOGYAPC AND STATUS INDICATOR ASSIGNMENTS FOR THE SCALP COOLING PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1520	S	1520

m. Optellem Lung Cancer Prediction (LCP) (APC 1508)

CPT code 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) became effective July 1, 2022. The Optellum LCP applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule. The risk score is used by the physician to quantify the risk of lung cancer and to help determine whether to refer the patient to a pulmonologist. For CY 2022, we assigned CPT code 0721T to APC New Technology 1508 (New Technology—Level 8 ($601–$700)).

This service became effective in the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data for use in CY 2023 ratesetting. Accordingly, for CY 2023, we propose to continue to assign CPT code 0721T to New Technology APC 1508 with a status indication of ''S''. The proposed New Technology APC and status indicator assignments for CPT code 0721T are found in Table 21.

TABLE 21: FINAL CY 2022 AND PROPOSED CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508	S	1508

n. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

CPT code 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session) became effective July 1, 2022. The QMRCP is a Software as a medical Service (SaaS) that performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. For CY 2022, we assigned CPT code 0723T to APC New Technology 1511 (New Technology—Level 11($900–$1,000)).

This service became effective in the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data. Accordingly, for CY 2023, we propose to continue to assign CPT code 0723T to New Technology APC 1511 with a status indicator of ''S''. The proposed New Technology APC and status indicator assignments for CPT code 0723T are found in Table 22.

TABLE 22: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	S	1511	S	1511

o. CardiAMP (APC 1574)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial[6] and the CardiAMP Cell Therapy Heart Failure Trial.[7] The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cells treatment for the following: (1) patients with medically refractory and symptomatic ischemic cardiomyopathy; and (2) patients with refractory angina pectoris and chronic myocardial ischemia. On April 1, 2022, we established HCPCS code C9782 to describe the CardiAMP cell therapy IDE studies and assigned HCPCS code C9782 to APC 1574 (New Technology—Level 37 ($9,501–$10,000)) with the status indicator ''T''. We subsequently revised the descriptor for HCPCS code C9782 to: (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (*e.g.,* mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (*e.g.,* transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study) to clarify the inclusion of the Helix transendocardial injection catheter device in the descriptor. Additionally, we determined that APC 1590 (New Technology—Level 39 ($15,001–$20,000)) most accurately accounts for the resources associated with furnishing the procedure described by HCPCS code C9782. We note that a transitional device pass-through application was submitted for the Helix transendorcardial injection catheter device for CY 2023. We direct readers to section IV.A of this proposed rule for a more detailed discussion of the transitional device pass-through applications.

This service became effective in the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data for use in CY 2023 ratesetting. Accordingly, for CY 2023, we propose to assign HCPCS code C9782 to New Technology APC 1590 with a status indication of ''T''. The proposed New Technology APC and status indicator assignments for HCPCS code C9782 are found in Table 23.

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[6] *ClinicalTrials.gov.* ''Randomized Controlled Pivotal Trial of Autologous Bone Marrow Cells Using the CardiAMP Cell Therapy System in Patients With Refractory Angina Pectoris and Chronic Myocardial Ischemia.'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT03455725?term=NCT03455725&rank=1.*

[7] *ClinicalTrials.gov.* ''Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell Therapy System in Patients With Post Myocardial Infarction Heart Failure.'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT02438306.*

TABLE 23: FINAL CY 2022 AND PROPOSED CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590	T	1590

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D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747) we finalized our proposal to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For this proposed rule, CY 2021 claims are generally the claims used for ratesetting and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2021 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for this proposed rule, we propose to designate four brachytherapy APCs and four clinical APCs as low volume APCs under the OPPS. The four brachytherapy APCs and 4 clinical APCs meet our criteria of having fewer than 100 single claims in the claims year used for ratesetting (CY 2021 for this CY 2023 OPPS/ASC proposed rule) and therefore, we propose that they would be subject to our low volume APC policy. These eight APCs were designated as low volume APCs in CY 2022; a ninth APC—APC 2647 (Brachytherapy, non-stranded, Gold-198)—was designated as a low volume APC for CY 2022 but did not meet our claims threshold for this proposed rule.

Table 24 includes the APC geometric mean cost without the low volume APC designation, that is, if we calculated the geometric mean cost based on CY 2021 claims data available for ratesetting; the median, arithmetic mean, and geometric mean cost using up to four years of claims data based on the APCs' designation as a low volume APC; and the statistical methodology we propose to use to determine the APC's cost for ratesetting purposes for CY 2023. As discussed in our CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data we proposed to use to calculate the costs for these APCs are CYs 2017, 2018, 2019, and 2021.

TABLE 24: COST STATISTICS FOR PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2023

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2023 APC Cost
2632	Iodine I-125 sodium iodide	9	$141.23	$31.74	$44.35	$37.26	$44.35
2635	Brachytx, non-str, HA, P-103	26	$125.24	$34.04	$51.09	$42.77	$51.09
2636	Brachy linear, non-str, P-103	0	---*	$49.65	$53.38	$38.80	$53.38
2647	Brachytx, NS, Non-HDRIr-192	14	$144.37	$184.49	$377.65	$141.18	$377.65
5244	Level 4 Blood Product Exchanges and Related Services	61	$44,995.52	$40,050.40	$42,322.34	$37,808.63	$42,322.34
5494	Level 4 Intraocular Procedures	52	$10,716.07	$16,498.85	$15,812.91	$12,394.87	$16,498.85
5495	Level 5 Intraocular Procedures	12	$11,280.14	$16,711.80	$15,595.47	$12,577.08	$16,711.80
5881	Ancillary Outpatient Services When Patient Dies	71	$7,882.93	$6,955.70	$12,301.75	$7,217.15	$12,301.75

* For this proposed rule, there are no CY 2021 claims that contain the HCPCS code assigned to APC 2636 (HCPCS code C2636) that are available for CY 2023 OPPS/ASC ratestting.

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E. OPPS APC-Specific Policies

1. Fractional Flow Reserve Derived From Computed Tomography (FFRCT) (APC 5724)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined

that we should pay separately for HeartFlow because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500. We did not have Medicare claims data in CY 2019 for CPT code 0503T, and we continued to assign the service to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50.

CY 2020 was the first year for which we had Medicare claims data to calculate the cost of HCPCS code 0503T. For the CY 2020 OPPS/ASC final rule with comment period, there were 957 claims with CPT code 0503T, of which 101 were single frequency claims that were used to calculate the geometric mean of the procedure. We planned to use the geometric mean to determine the cost of HeartFlow for purposes of determining the appropriate APC assignment for the procedure. However, the number of single claims for CPT code 0503T was below the New Technology APC low-volume payment policy threshold for the proposed rule, and this number of single claims was only two claims above the threshold for the New Technology APC low-volume policy for the final rule. Therefore, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our New Technology APC low-volume payment policy. While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for HeartFlow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was $768.26, the arithmetic mean cost for CPT code 0503T was $960.12, and the median cost for CPT code 0503T was $900.28. Of the three cost methods, the highest amount was for the arithmetic mean, which fell within the cost band for New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50. The arithmetic mean also helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T. Specifically, using CY 2019 data, we identified 3,188 claims billed with CPT code 0503T including 465 single frequency claims. These totals were well above the threshold of 100 claims for a procedure to be evaluated using the New Technology APC low-volume policy. Therefore, we used our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T. Our analysis found that the geometric mean for CPT code 0503T was $804.35, and the geometric mean cost for the service fell within the cost band for New Technology APC 1510 (New Technology—Level 10 ($801–$900)). However, providers and other stakeholders noted that the FFRCT service costs $1,100 and that there are additional staff costs related to the submission of coronary CT image data for processing by HeartFlow.

We noted that HeartFlow was one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers were learning how to accurately report their charges to Medicare when billing for artificial intelligence services (85 FR 85943). This especially appeared to be the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Therefore, we decided it would be appropriate to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2021 as in CY 2020 in order to provide payment stability and equitable payment for providers as they continued to become familiar with the proper cost reporting for HeartFlow and other artificial intelligence services. Accordingly, we assigned CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50 for CY 2020, and we continued to assign CPT code 0503T to New Technology APC 1511 for CY 2021.

For CY 2022, we used claims data from CY 2019 to estimate the cost of the HeartFlow service. Because we were using the same claims data as in CY 2021, these data continued to reflect that providers were learning how to accurately report their charges to Medicare when billing for artificial intelligence services. Therefore, we continued to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2022 as in CY 2020 and CY 2021: New Technology APC 1511 (New Technology—Level 11 ($901–$1000)), with a payment rate of $950.50 for CY 2022, which was the same payment rate for the service as in CY 2020 and CY 2021.

For CY 2023, we have three years of claims data from CY 2018, CY 2019, and CY 2021 for CPT code 0503T to review to determine whether there is an appropriate clinical APC to assign the HeartFlow service. First, we have sufficient single frequency claims from these three years to have a reliable estimate of the cost of the service. There were 101 single frequency claims in CY 2018, 465 single frequency claims in CY 2019, and 1,681 single frequency claims in CY 2021. The estimated cost of 0503T has been reasonably consistent over the same three years as well. The estimated cost of HeartFlow was around $768 in CY 2018, around $808 in CY 2019, and around $827 in CY 2021. Since the cost data have been stable for HeartFlow, we can assign it to a clinical APC using our regular process of using the most recent year of claims data for a procedure. HeartFlow is a diagnostic service, and the OPPS has a clinical APC series for diagnostic tests and related services, with the cost of 0503T based on claims data falling between Level 3, with a payment rate of around $498, and Level 4, with a payment rate of around $961. Since the geometric mean cost of HCPCS code 0503T is $827, and $827 is closer to $961 than $498, the best APC assignment for the HeartFlow procedure appears to be APC 5724 (Level 4 Diagnostic Tests and Related Services).

Therefore, we propose for CY 2023 to assign CPT code 0503T to clinical APC 5724 (Level 4 Diagnostic Tests and Related Services). Table 25 shows the current and proposed status indicator and APC assignment for 0503T. We refer readers to Addendum B of this proposed rule for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 25: FINAL CY 2022 AND PROPOSED CY 2023OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0503T

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0503T	Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model	S	1511	S	5724

2. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66807 through 66808), we finalized a restructuring of what were previously several neurostimulator procedure-related APCs into a four-level series. Since CY 2015, the four-level APC structure for the series has remained unchanged. In addition to that restructuring, in the CY 2015 OPPS/ASC final rule with comment period, we also made the Levels 2 through 4 APCs comprehensive APCs (79 FR 66807 through 66808). Later, in the CY 2020 OPPS/ASC final rule with comment period, we also made the Level 1 Neurostimulator and Related Procedure APC (APC 5461) a comprehensive APC (84 FR 61162 through 61166).

In reviewing the claims data available for the CY 2021 OPPS/ASC proposed rule, we believed that it was appropriate to create an additional Neurostimulator and Related Procedures level, between what were then the Levels 2 and 3 APCs. Creating this APC allowed for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPPS, we finalized a five-level APC structure for the Neurostimulator and Related Procedures series (85 FR 85968 through 85970). In addition to creating the new level, we also assigned CPT code 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) to the new Level 3 APC (85 FR 85970).

Some commenters have requested that we create a Level 6 Neurostimulator and Related Procedures APC, due to their concerns around clinical and resource cost similarity in the Level 5 Neurostimulator and Related Procedures APC. Based on our review of the data available for this CY 2023 OPPS/ASC proposed rule, we believe that the five-level structure for the Neurostimulator and Related Procedures APC series remains appropriate. The proposed geometric mean cost for the Level 5 Neurostimulator and Related Procedures is $30,198.36 with the geometric means of cost significant codes in Level 5 ranging from approximately $28,000 to $36,000, which is well within the range of the 2 times rule. In addition, a review of the clinical characteristics of the services in the APC suggests that the current structure is appropriate. Finally, as discussed in the CY 2021 OPPS/ASC final rule with comment period, we reiterate that the OPPS is a prospective payment system. We group procedures with similar clinical characteristics and resource costs into APCs and establish a payment rate that reflects the geometric mean of all services in the group even though the cost of each service within the APC may be higher or lower than the APC's geometric mean. As a result, in the OPPS any individual procedure may potentially be overpaid or underpaid because the payment rate is based on the geometric mean of the entire group of services in the APC. However, the impact of these payment differences should be mitigated when distributed across a large number of APCs. (85 FR 85968).

While we are not proposing any changes in the CY 2023 OPPS to the 5-level structure of the Neurostimulator and Related Procedures APC series in this proposed rule, we recognize the commenters' concerns regarding the granularity of the current APC levels and their request to create an additional level to address such concerns. Accordingly, we are soliciting comments on the potential creation of a new Level 6 APC from the current Level 5 within the Neurostimulator and Related Procedures APC series, which would include the following codes:

- 0266T: Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)
- 0268T: Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)
- 0424T: Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system

(transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)

• 0431T: Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only

• 64568: Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

In summary, for the CY 2023, we propose to maintain the current 5-level structure for the Neurostimulator and Related Procedure APC series. However, we are also soliciting comment from stakeholders on the creation of an additional Level 6 APC in the series from the current Level 5 APC. See Table 26 below for the proposed CY 2023 for the Neurostimulator and Related Procedures APCs.

TABLE 26: PROPOSED CY 2023 NEUROSTIMULATOR AND RELATED PROCEDURES APCS

APC	Group Title	SI	Proposed CY 2023 Proposed APC Geometric Mean Cost	6-Level Alternative APC Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,491.49	$3,491.49
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,808.24	$6,808.24
5463	Level 3 Neurostimulator and Related Procedures	J1	$12,980.43	$12,980.43
5464	Level 4 Neurostimulator and Related Procedures	J1	$22,059.02	$22,059.02
5465	Level 5 Neurostimulator and Related Procedures	J1	$30,198.36	$29,434.26
5466	Level 6 Neurostimulator and Related Procedures	J1	N/A	$33,947.12

3. Urology and Related Services (APCs 5371 Through 5378)

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85984 through 85986), we finalized a reorganization of the Urology and Related Services APCs from what was previously a seven-level series of related APCs into an eight-level series. In addition to creating the Urology and Related Services APC 5378 (Level 8 Urology and Related Services), and finalizing the reassignment of several urology procedures, we also revised the APC assignment for CPT 53440 (Male sling procedure) and CPT 0548T (Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy) from APC 5376 to APC 5377. We believed the CY 2021 reorganization appropriately addressed the resource costs for the procedures whose geometric mean costs were between APC 5376 and APC 5377. Since CY 2021, the eight-level APC structure for the series has remained unchanged.

In our annual review of the CY 2021 claims submitted between January 1, 2021 through December 31, 2021 and processed on or before December 31, 2021, we examined the procedures assigned to the Urology Procedures APCs. In the CY 2022 final rule with comment period (86 FR 63565), we received comments requesting that CPT code 55880 be reassigned from APC 5375 (Level 5 Urology and Related Services) to APC 5376 (Level 6 Urology and Related Services). We remind readers that, for the CY 2022 ratesetting, we used the CY 2019 claims data due to the PHE. For CY 2022, we did not finalize any APC reassignment because our data analysis using the CY 2019 claims did not support the impact on the urology APCs' geometric means. For the CY 2023 ratesetting, we propose to use CY 2021 claims data. Using the CY 2021 claims data, we identified eight procedures (listed below) from APC 5375 whose geometric mean ranged between the geometric means for APC 5375 and APC 5376. The geometric means of these services are closer to the geometric mean of APC 5376, which is $8,788.53, than the geometric mean of APC 5375, which is $4,826.23. This reassignment to APC 5476 improves the resource cost and clinical homogeneity for the procedures within APC 5375 and APC 5376. Below is a list of the procedures and their geometric mean costs that we propose to reassign from APC 5375 to APC 5376 for CY 2023.

• CPT 50576: Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy (Geometric mean cost: $11,137.98)

• HCPCS C9769: Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (Geometric mean cost: $7,742.45)

• CPT 51860: Cystorrhaphy, suture of bladder wound, injury or rupture; simple (Geometric mean cost: $7,548.83)

• CPT 0549T: Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy (Geometric mean cost: $7,337.54)

• CPT 53449: Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff (Geometric mean cost: $7,109.79)

• CPT 54344: Repair of hypospadias complication(s) (ie, fistula, stricture, diverticula); requiring mobilization of skin flaps and urethroplasty with flap or

patch graft (Geometric mean cost: $7,005.64)

• CPT 54316: Urethroplasty for second stage hypospadias repair (including urinary diversion) with free skin graft obtained from site other than genitalia (Geometric mean cost: $7,069.06)

• CPT 55880: Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance (Geometric mean cost: $7,015.62)

In summary, for the CY 2023, we propose to reassign eight procedures from APC 5375 to APC 5376 for the Urology and Related Procedure APC series. Table 27 below shows the proposed geometric mean cost for each APC with reassignment of the eight procedures.

TABLE 27: PROPOSED CY 2023 UROLOGY AND RELATED SERVICES APCs

APC	Group Title	SI	Proposed CY 2023 Proposed APC Geometric Mean Cost With Reassignment
5371	Level 1 Urology and Related Services	J1	$226.14
5372	Level 2 Urology and Related Services	J1	$643.47
5373	Level 3 Urology and Related Services	J1	$1,906.74
5374	Level 4 Urology and Related Services	J1	$3,289.11
5375	Level 5 Urology and Related Services	J1	$4,826.23
5376	Level 6 Urology and Related Services	J1	$8,788.53
5377	Level 7 Urology and Related Services	J1	$12,357.80
5378	Level 8 Urology and Related Services	J1	$19,806.45

4. Unlisted Dental Procedure/Service (APC 5871)

For CY 2022, CPT code 41899 (Unlisted procedure, dentoalveolar structures) is assigned to APC 5161 (Level 1 ENT Procedures). Unlisted codes, like CPT 41899, do not describe any specific procedure or service, so they lack the specificity needed to describe the resources used. As a reminder, the fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that the drug, device, procedure, or service is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment. Unlisted codes provide a way for providers to report services for which there is no HCPCS code that specifically describes the service furnished. Because of the lack of specificity, unlisted codes are generally assigned to the lowest level APC within the most appropriate clinically related APC group under the OPPS. However, we believe that APC 5161 (Level 1 ENT Procedures) is not the most clinically appropriate APC series for this code. While APC 5161 includes some dental services, we believe that CPT code 41899 is more closely aligned clinically to the dental services in APC 5871 (Dental Procedures), which is the sole APC where dental procedures described by the Current Dental Terminology (CDT) reside. Therefore, for CY 2023, we propose to reassign HCPCS code 41899 to clinical APC 5871, which is the only, and therefore lowest, APC group that specifically describes dental procedures.

While we do not consider costs for services described by unlisted codes for rate setting purposes, based on both our established policy of generally assigning these codes to the lowest level APC within the most appropriate, clinically related APC group, and our inability to determine the specific services the unlisted code describes, we would note that the geometric mean cost for CPT code 41899 is more closely aligned with the geometric mean cost of other dental procedures in APC 5871 than with its current APC assignment. Specifically, in our annual review of the CY 2021 claims submitted between January 1, 2021 through December 31, 2021 and processed on or before December 31, 2021, the geometric mean cost for CPT code 41899 was $2,310.47, while the geometric mean cost of the code's current APC assignment, APC 5161, was $203.64. In contrast, the geometric mean cost of APC 5871 (Dental Procedures) was $1,958.92.

Table 28 below shows the current and proposed status indicator and APC assignment for CPT code 41899. We refer readers to Addendum B of this proposed rule for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 28: CY 2023 PROPOSED OPPS APC AND STATUS INDICATOR FOR CPT CODE 41899

CPT Code	Long Descriptor	CY 2022 OPPS SI	CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
41899	Unlisted procedure, dentoalveolar structures	T	5161	S	5871

5. COVID–19 and Monoclonal Antibody Administration Services

a. Statutory and Regulatory Background

Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L 116–136, March 27, 2020) provides for coverage of the COVID–19 vaccine under Part B of the Medicare program without any beneficiary cost sharing. Specifically, section 3713 added the COVID–19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. Additionally, section 3713(e) of the CARES Act authorizes CMS to implement the amendments made by section 3713 ''through program instruction or otherwise.'' The changes to section 1861(s)(10)(A) of the Act were effective on the date of enactment, that is, March 27, 2020, and apply to a COVID–19 vaccine beginning on the date that such vaccine is licensed under section 351 of the PHS Act (42 U.S.C. 262).

We discussed our implementation of section 3713 in the interim final rule with comment period titled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' published in the November 6, 2020 **Federal Register** (85 FR 71145 through 71150). In that rule, we stated that, while section 3713(e) of the CARES Act authorizes us to implement the amendments made by that section through program instruction or otherwise, we believed it was important to clarify our interpretation of section 3713 and announce our plans to ensure timely Medicare Part B coverage and payment for the COVID–19 vaccine and its administration. We anticipated that payment rates for the administration of other Part B preventive vaccines and related services, such as the flu and pneumococcal vaccines, would inform the payment rates for administration of COVID–19 vaccines. In the same interim final rule, we stated that, as soon as practicable after the authorization or licensure of each COVID–19 vaccine product by FDA, we would announce the interim coding and a payment rate for its administration (or, in the case of the OPPS, an APC assignment for each vaccine product's administration code), taking into consideration any product-specific costs or considerations involved in furnishing the service. We further stated that the codes and payment rates would be announced through technical direction to the Medicare Administrative Contractors (MACs) and posted publicly on the CMS website.

In December 2020, we publicly posted the applicable CPT codes for the Pfizer-BioNTech and Moderna COVID–19 vaccines and initial Medicare payment rates for administration of these vaccines upon FDA's authorization of them. We announced an initial Medicare payment rate for COVID–19 vaccine administration of $28.39 to administer single-dose vaccines. For a COVID–19 vaccine requiring a series of two or more doses—for example, for both the Pfizer-BioNTech and Moderna products—we announced a payment rate for administration of the initial dose(s) of $16.94, which was based on the Medicare payment rate for administering the other preventive vaccines under section 1861(s)(10) of the Act. We also announced a payment rate for administering the second dose of $28.39.[8] CMS continues to establish product-specific HCPCS codes for each COVID–19 vaccine product on a rolling basis as they are authorized by the FDA. On March 15, 2021, we announced an increase in the payment rate for administering a COVID–19 vaccine to $40 per dose, effective for doses administered on or after March 15, 2021. For additional information, on timing and payment rates for COVID–19 vaccine administration, please see the CMS website: *https://www.cms.gov/medicare/preventive-services/covid-19-services-billing-coverage/covid-19/medicare-covid-19-vaccine-shot-payment*.

b. Payment for COVID–19 Vaccine Administration Services Under the OPPS

Under the OPPS, separate payment is made for the COVID–19 vaccine product and its administration. Except when the provider receives the COVID–19 vaccine for free (as has been the case to date), providers are paid for COVID–19 vaccine products at reasonable cost, as is the case with influenza and pneumococcal vaccines.[9] The HCPCS codes associated with the vaccine products are assigned OPPS status indicator ''L'' to indicate that they are paid at reasonable cost and are exempt from coinsurance and deductible payments under sections 1833(a)(3) and 1833(b) of the Act.

While COVID–19 and other preventive vaccine products are paid based on reasonable cost under the OPPS, the payment rates for the COVID–19 vaccine administration HCPCS codes are based on the APCs to which the codes are assigned. Because COVID–19 vaccination can involve more than one dose, we established APCs 9397 (COVID–19 Vaccine Admin Dose 1 of 2) and 9398 (COVID–19 Vaccine Admin

[8] Medicare COVID–19 Vaccine Shot Payment. CMS website. *https://www.cms.gov/medicare/preventive-services/covid-19-services-billing-coverage/covid-19/medicare-covid-19-vaccine-shot-payment#:~:text=%2416.94%20for%20the%20initial%20dose,final%20dose%20in%20the%20series.*

[9] COVID–19 Vaccines and Monoclonal Antibodies. CMS website. *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

Dose 2 of 2, Single Dose Product or Additional Dose) to appropriately identify and pay for the administration of the COVID–19 vaccines. In CY 2021, we announced the establishment of APCs 9397 and 9398 for the COVID–19 vaccine administration codes through the April 2021 OPPS Update CR (Transmittal 10666, Change Request 12175 dated March 8, 2021). Prior to March 15, 2021, APC 9397 for the first dose of the COVID–19 vaccine was assigned a payment rate of $16.94; and APC 9398 for the second dose was assigned a payment rate of $28.39. As described above, we changed the payment rate to $40 per dose for the first, second, and booster dose(s) of the COVID–19 vaccine effective March 15, 2021.

For CYs 2021 and 2022, we maintained the payment rate of $40 for the APCs to which the COVID–19 vaccine administration services are assigned. For further information please see Addendum B on the CY 2021 and 2022 OPPS websites.

As of July 1, 2022, there are approximately 18 COVID–19 vaccine administration HCPCS codes. These codes are listed in Table 29 below. We note that the latest list of HCPCS codes for COVID–19 vaccine products and vaccine administration, along with their effective dates and payment rates, is available on the CMS COVID–19 Vaccines and Monoclonal Antibodies website at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

Based on our review of CY 2021 claims data associated with the COVID–19 vaccine administration HCPCS codes, the geometric mean cost for APC 9397 is $25.86 and the geometric mean cost for APC 9398 is $36.80. We note that CY 2021 utilization of the COVID–19 vaccine administration codes in the outpatient hospital setting was very high, with nearly 7 million claims for these codes in that year and may not be reflective of future year utilization. Since we do not know if demand for COVID–19 vaccine administration in the outpatient hospital setting will be significantly different in CY 2023 than CY 2021 because CY 2021 was the first complete year for which we had COVID–19 vaccine administration claims data, and because we do not know if the PHE for COVID–19 will be in effect in CY 2023, we believe that we should maintain the $40 per dose payment rate for the COVID–19 administration HCPCS codes in CY 2023 until we have an additional year of claims data on which to base the payment rate. Therefore, for CY 2023 we propose to use the equitable adjustment authority at 1833(t)(2)(E) to maintain the payment rate of $40 for each of the COVID–19 vaccine administration APCs 9397 and 9398. We believe maintaining the current, site neutral, payment rate is necessary to ensure equitable payments during the continuing PHE and at least through the end of CY 2023. We refer readers to Table 29 below for the proposed payment rates for the COVID–19 vaccine administration HCPCS codes.

We also note that this policy does not pertain to OPPS payment for monoclonal antibody products used for COVID–19 and their administration. The OPPS payment rates for administration of COVID–19 monoclonal antibody products under the Part B preventive vaccine benefit are set at the midpoint of the cost bands for the New Technology APCs to which the monoclonal antibody administration services are assigned under the OPPS. We assigned COVID–19 monoclonal antibody administration services to New Technology APCs based on estimated costs for these services.

c. Use of Alternative Site-Neutral Methodology To Update Payment Rates for COVID–19 Vaccine Administration Services for CY 2023

Under current policy, the payment rates for COVID–19 vaccine administration services are site-neutral across most outpatient and ambulatory settings. We request comment on whether we should continue a site-neutral payment policy for COVID–19 vaccine administration for CY 2023, and what alternative approaches (including under our equitable adjustment authority at 1833(t)(2)(E)) may be appropriate to update the OPPS payment rates for the COVID–19 vaccine administration HCPCS codes (including the in-home add-on HCPCS code M0201) while continuing to ensure site-neutral payment for these services. For example, in the CY 2023 PFS proposed rule that will be included in the July 29, 2022 **Federal Register**, we are proposing to update the payment rate for the administration of preventive vaccines (other than for COVID–19 and other than for services paid under other payment systems such as the OPPS) using the annual increase to the Medicare Economic Index (MEI). We request public comments on whether, as an alternative to our proposal to maintain current OPPS payment rates for COVID–19 vaccine administration using our equitable adjustment authority at section 1833(t)(2)(E), we should instead use the rate finalized through PFS rulemaking that generally applies under the preventive vaccine benefit, or an alternative method commenters suggest, to determine the appropriate payment rates for preventive vaccine administration under the OPPS, which would likely also require use of our equitable adjustment authority.

For more information on the payment rates for the administration of preventive vaccines, including the proposal to update the payment rate by the annual increase to the MEI, we refer readers to the CY 2023 PFS proposed rule that will be included in the July 29, 2022 **Federal Register**.

We are also seeking comment on whether to use the rate finalized through PFS rulemaking generally as it applies under the preventive vaccine benefit, or an alternative method commenters suggest, to set the CY 2023 payment rate for HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*).

In summary, for CY 2023, we are proposing to continue to pay $40 per dose for the administration of the COVID–19 vaccines provided in the HOPD setting, and an additional $35.50 for the administration of the COVID–19 vaccines when provided under certain circumstances in the patient's home, in CY 2023. Additionally, we request comments on whether, as an alternative to maintaining the CY 2022 OPPS payment rates for COVID–19 vaccine administration services in CY 2023, we should use a different approach, including relying on our equitable adjustment authority in section 1833(t)(2)(E) to base the payment rate for COVID–19 vaccine administration under the OPPS in CY 2023 on the payment rate for the COVID–19 vaccine administration under the preventive vaccine benefit under Part B as finalized in PFS rulemaking, or employing another alternate methodology to set CY 2023 payment rates for these services.

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TABLE 29: PROPOSED CY 2023 SI, APCS, AND PAYMENT RATES FOR COVID-19 ADMINISTRATION SERVICES

HCPCS Code	Short Descriptor	CY 2022 OPPS SI	CY 2022 OPPS APC	CY 2022 OPPS Payment	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Proposed CY 2023 OPPS Payment
M0201	Covid-19 vaccine home admin	S	1494	$35.50	S	1494	$35.50
0001A	Adm sarscov2 30mcg/0.3ml 1st	S	9397	$40.00	S	9397	$40.00
0002A	Adm sarscov2 30mcg/0.3ml 2nd	S	9398	$40.00	S	9398	$40.00
0003A	Adm sarscov2 30mcg/0.3ml 3rd	S	9398	$40.00	S	9398	$40.00
0004A	Adm sarscov2 30mcg/0.3ml bst	S	9398	$40.00	S	9398	$40.00
0011A	Adm sarscov2 100mcg/0.5ml1st	S	9397	$40.00	S	9397	$40.00
0012A	Adm sarscov2 100mcg/0.5ml2nd	S	9398	$40.00	S	9398	$40.00
0013A	Adm sarscov2 100mcg/0.5ml3rd	S	9398	$40.00	S	9398	$40.00
0031A	Adm sarscov2 vac ad26 .5ml	S	9398	$40.00	S	9398	$40.00
0034A	Adm sarscov2 vac ad26 .5ml b	S	9398	$40.00	S	9398	$40.00
0051A	Adm sarscv2 30mcg trs-sucr 1	S	9397	$40.00	S	9397	$40.00
0052A	Adm sarscv2 30mcg trs-sucr 2	S	9398	$40.00	S	9398	$40.00
0053A	Adm sarscv2 30mcg trs-sucr 3	S	9398	$40.00	S	9398	$40.00
0054A	Adm sarscv2 30mcg trs-sucr b	S	9398	$40.00	S	9398	$40.00
0064A	Adm sarscov2 50mcg/0.25mlbst	S	9398	$40.00	S	9398	$40.00
0071A	Adm sarscv2 10mcg trs-sucr 1	S	9397	$40.00	S	9397	$40.00
0072A	Adm sarscv2 10mcg trs-sucr 2	S	9398	$40.00	S	9398	$40.00
0073A	Adm sarscv2 10mcg trs-sucr 3	S	9398	$40.00	S	9398	$40.00
0094A	Adm sarscov2 50 mcg/.5 mlbst	S	9398	$40.00	S	9398	$40.00

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d. Comment Solicitation on the Appropriate Payment Methodology for Administration of Preventive Vaccines Post PHE

Currently, under the OPPS, the codes describing the administration of the influenza, pneumococcal, and hepatitis b vaccines are assigned to APC 5691 (Level 1 Drug Administration), with a payment rate of about $40. However, given that the statutory benefit for Medicare Part B preventive vaccines and their administration is based on 1861(s)(10) of the Act, we are seeking comments on whether we should adopt a different methodology to make payment when these services are furnished by a HOPD other than the one for covered OPD services under section 1833(t) of the Act. Therefore, in this proposed rule, we are seeking comments on the appropriate payment methodology for the administration of Part B preventive vaccines, including the COVID–19 vaccine post PHE.

e. COVID–19 Monoclonal Antibody Products and Their Administration Services Under OPPS

Subsequent to the November 6, 2020 IFC and as discussed in the CY 2022 PFS final rule (86 FR 65190 through 65194), when monoclonal antibody products for COVID–19 treatment were granted EUAs during the PHE for COVID–19, we made the determination to cover and pay for them under the Part B vaccine benefit in section 1861(s)(10) of the Act

Regarding availability of COVID–19 monoclonal antibody products, there are no monoclonal antibody products approved for the treatment or prevention of COVID–19. There are five authorized monoclonal antibody COVID–19 products; four are authorized for the treatment or post-exposure prophylaxis for prevention of COVID–19 and one is authorized as pre-exposure prophylaxis for prevention of COVID–19.[10] We note that none of the four monoclonal antibody products for treatment or post-exposure prevention of COVID–19 that have been granted an EUA are authorized for use in geographic regions where infection was likely caused by a non-susceptible variant. Due to data indicating decreased activity for three of these treatments against Omicron variants currently in wide circulation, only one of these treatments is currently authorized in any U.S. region until further notice by FDA.

Consistent with how we pay for COVID–19 vaccine products and their administration, under the OPPS, we pay separately for COVID–19 monoclonal antibodies and their administration. Except when the provider receives the COVID–19 monoclonal antibody product for free, providers are paid for these products at reasonable cost.[11] The HCPCS codes associated with the COVID–19 monoclonal antibody products are assigned OPPS status indicator ''L'' to indicate that they are paid at reasonable cost and are exempt from coinsurance and deductible payments under sections 1833(a)(3) and 1833(b) of the Act.

While the COVID–19 monoclonal antibody products are paid based on reasonable cost under the OPPS, the payment rates for the COVID–19 monoclonal antibody product administration depends on the route of administration and whether the product is furnished in a healthcare setting or in the beneficiary's home. As discussed in more detail in the CMS COVID–19 Monoclonal Toolkit,[12] payment for administration of monoclonal antibodies can range from $150.50 to $750.00. The HCPCS codes associated with the COVID–19 monoclonal antibody product administration are assigned to New Technology APCs 1503, 1504, 1505, 1506, 1507, and 1509 with an OPPS status indicator ''S'' (Procedure or Service, Not Discounted When Multiple, separate APC assignment) to indicate that the administration of monoclonal antibodies is paid separately under the OPPS.

For CYs 2021 and 2022, we maintained the payment rates for the COVID–19 monoclonal antibody product administration services by maintaining their New Technology APCs assignments. For further information, please see Addendum B on the CY 2021 and 2022 OPPS websites. For CY 2023, we propose to use the equitable adjustment authority at 1833(t)(2)(E) to maintain the CY 2022 New Technology APC assignments (specifically, New Technology APCs 1503, 1504, 1505, 1506, 1507, or 1509) and corresponding payment rates for each of the COVID–19 monoclonal antibody product administration HCPCS codes for as long as these products are considered to be covered and paid under the Medicare Part B vaccine benefit so that, if the PHE ends, the benefit category and corresponding payment methodology under the OPPS will remain site neutral.

We note that, once these products are no longer considered to be covered and paid under the Medicare Part B vaccine benefit, we would expect the COVID–19 monoclonal antibody product administration services to be paid similar to monoclonal antibody products used in the treatment of other health conditions—to be ''biologicals''. For more background on Medicare Part B payment for COVID–19 monoclonal antibody products and their administration, and for current proposals regarding such payment, we refer readers to the CY 2023 PFS proposed rule that will be included in the July 29, 2022 **Federal Register**. In particular, the CY 2023 PFS proposed rule proposes to clarify that the COVID–19 monoclonal antibody products would be covered and paid for under the Medicare Part B vaccine benefit until the end of the calendar year in which the March 27, 2020 EUA declaration for drugs and biologics is terminated. Additionally, we are proposing to continue the existing policy to pay for monoclonal antibody COVID–19 pre-exposure prophylaxis products and their administration under the Part B vaccine benefit even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization.

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). 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 § 419.66(g) provided that this pass-

[10] Viewed 5/6/2022. *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

[11] COVID–19 Vaccines and Monoclonal Antibodies. CMS Website *http://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

[12] *https://www.cms.gov/monoclonal.*

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 had 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 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).

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 current device pass-through payment policy.[13]

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. Currently, there are 11 device categories eligible for pass-through payment. These devices are listed in Table 30 where we detail the expiration dates of pass-through payment status for each of the 11 devices currently receiving device pass-through payment.

In the CY 2022 OPPS/ASC final rule with comment period we used CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting (86 FR 63755). As a result, we utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status expired between December 31, 2021 and September 30, 2022 to mimic continued pass-through payment, promote adequate access to innovative therapies for Medicare beneficiaries, and gather sufficient data for purposes of assigning these devices to clinical APCs (86 FR 63755). A full discussion of this finalized policy is included in section X.F of the CY 2022 OPPS/ASC final rule with comment (86 FR 63755). In section X.B of this proposed rule, we propose to resume the regular update process of using claims from the year 2 years prior to the year for which we are setting rates, specifically CY 2021 outpatient claims for CY 2023 OPPS ratesetting. Based on CMS's policy proposal in section X.B we are not proposing to provide any additional quarters of separate payments for any device category whose pass-through payment status will expire between December 31, 2022 and September 30, 2023. We seek comment on how the circumstances for CY 2023 are similar to those in CY 2022, when we adopted the equitable adjustment to mimic continued pass-through status for drugs, biologicals, and a device category with pass-through status that expired between December 31, 2021, and September 30, 2023.

We utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters in CY 2022 for C1823, as its pass-through payment status expired on December 31, 2021 (86 FR 63570). Separate payment for HCPCS code C1823 under our equitable adjustment authority will end on December 31, 2022. Table 30 includes this date for the device described by HCPCS code C1823 and includes the specific expiration dates for devices with pass-through status expiring at the end of the fourth quarter of 2022, in 2023, or in 2024.

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[13] To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act (PRA). This collection (CMS–10052) has an OMB control number of 0938–0857 and an expiration date of 11/30/2022. The application is currently undergoing the PRA reapproval process, which has notice and comment periods separate from this proposed rule. The 60-day notice was published in the **Federal Register** on April 29, 2022 (87 FR 25488).

TABLE 30: DEVICES WITH PASS-THROUGH STATUS (OR ADJUSTED SEPARATE PAYMENT) EXPIRING AT THE END OF THE FOURTH QUARTER OF 2022, IN 2023, OR IN 2024

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2022*
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024

* We utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters of CY 2022 for C1823 whose pass-through payment status expired on December 31, 2021. Adjusted separate payment for HCPCS code C1823 will end on December 31, 2022.

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2. New Device Pass-Through Applications for CY 2023

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 are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization 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;

• 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

• 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 cost 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 cryoablation, 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, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of 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).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website 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 Status for CY 2023

We received nine complete applications by the March 1, 2022 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2023 OPPS/ASC proposed rule. We received one of the applications in the second quarter of 2021, one of the applications in the third quarter of 2021, two of the applications in the fourth quarter of 2021, and five of the applications in the first quarter of 2022. One of the applications was approved for device pass-through status during the quarterly review process: the aprevo™ Intervertebral Body Fusion, which received quarterly approval under the alternative pathway effective October 1, 2021. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, aprevo™ Intervertebral Body Fusion is discussed in section IV.2.b.1 of this proposed rule.

Applications received for the later deadlines for the remaining 2022

quarters (the quarters beginning June 1, September 1, and December 1 of 2022), if any, will be discussed in the CY 2024 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*.

Discussions of the applications we received by the March 1, 2022 deadline are included below.

1. Alternative Pathway Device Pass-Through Applications

We received two device pass-through applications by the March 2022 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation, and therefore are eligible to apply under the alternative pathway.

(1) Aprevo™ Intervertebral Body Fusion Device

Carlsmed, Inc. submitted an application for a new device category for transitional pass-through payment status for aprevo™ Intervertebral Fusion Device (aprevo™) for CY 2023. Per the applicant, the device is an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures indicated for the treatment of spinal deformity. The applicant stated that the implant device is custom made for patient-specific features using patient computed tomography (CT) scans to create 3D virtual models of the deformity to be used during anterior lumbar interbody fusion, lateral lumbar interbody fusion, and transforaminal lumbar interbody fusion procedures. The aprevo™ device is additively manufactured and made from Titanium Alloy (Ti-6Al-4V) per ASTM F3001, and has a cavity intended for the packing of bone graft. In addition, the applicant explained that aprevo™ is used with supplemental fixation devices and bone graft packing. Per the applicant, the device was formerly known as ''Corra™.''

According to the applicant, the surgical correction plan for adult patients with spinal deformity is significantly more complex than performing a spine fusion for a degenerative spinal condition. The applicant further described that these deformity correction plans require numerous complex measurements and calculations that consider a multitude of relationships between each area of the spine (cervical, thoracic, lumbar), the 33 individual levels of the spine, the pelvis, hips, and other reference points in relation to normal values based on the patient's age. The applicant stated that achieving the proper balance between these factors has been shown to directly contribute to improved clinical outcomes and increased patient satisfaction. Despite the use of sophisticated planning tools, surgeons are frequently unable to obtain the planned correction, and this is often because stock devices, which are not patient-specific, do not match the specific geometry that is required to realign each level of the individual patient's spine. The applicant claims that aprevo™ devices provide the precise geometry to match the planned surgical correction for a spinal deformity patient, and they maintain this precise position while the bones fuse together in their new alignment.

According to the applicant, aprevo™ devices are surgically placed between two vertebral levels of the spine. The approach may be from the front, side, or back of the patient. The surgeon will gently clear away the disc material (which is often degenerated) before placing the device. Bone graft is placed inside a central opening of the interbody device. This allows the patient's bone to integrate with the graft material and form a bony bridge.

The applicant asserted that there are no other devices in the market like aprevo™. Per the applicant, other stock devices do not match the anatomy of each patient precisely. The applicant stated, in contrast, aprevo™ utilizes 3D generated reconstructions of each level of the patient's lumbar spine that match the anatomy of the patient. Per the applicant, the device's upper and lower surfaces match the topography of the patient's bone as this is important because the surfaces of the vertebral endplates can be extremely bumpy or wavy and sometimes thin and fragile. Per the applicant, by having a fit that matches these contours, the high loads that result from body weight are more evenly distributed across the surface. The applicant stated that this contributes to faster healing of the bone and lessens the risk of having high stress points that could result in a stock interbody device breaking through the thin endplate.

Aprevo™ is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had 6 months of non-operative treatment. The devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches may include anterior lumbar interbody fusion or lateral lumbar interbody fusion.

With respect to the newness criterion at § 419.66(b)(1), aprevo™ received FDA Breakthrough Device designation under the name ''Corra'' on July 1, 2020 for the Corra Anterior, Corra Transforaminal, and Corra Lateral Lumbar Fusion System interbody device which is intended for use in anterior lumbar interbody fusion, lateral lumbar interbody fusion, and transforaminal lumbar interbody fusion under this designation. The applicant received 510(k) clearance from FDA for the Intervertebral Body Fusion Device (anterior lumbar interbody fusion and aprevo™ lateral lumbar interbody fusion devices) on December 3, 2020. The applicant also received 510(k) clearance from FDA for the Transforaminal Intervertebral Body Fusion (IBF) device on June 30, 2021. We received the application for a new device category for transitional pass-through payment status for aprevo™ on May 27, 2021, which is within 3 years of the date of the initial FDA marketing authorization of both indications. We are inviting public comment on whether aprevo™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, aprevo™ is integral to the service provided, is used for one patient only, comes in contact with human tissue and is surgically inserted in a patient until the procedure is completed. The applicant also claimed that aprevo™ 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. We are inviting public comments on whether aprevo™ meets the eligibility criteria at § 419.66(b).

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. The applicant describes aprevo™ as an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures indicated for the treatment of spinal deformity. Per the applicant, no previous device categories for pass-through payment have encompassed the device. In addition, per the applicant, the possible existing pass-through codes: C1821 (Interspinous process distraction device (implantable)), C1776 (Joint device (implantable)), C1734 (Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to-bone), and C1062 (Intravertebral body fracture augmentation with implant (*e.g.,* metal, polymer)) do not appropriately describe aprevo™ because none of the existing codes pertain to a patient-specific spinal interbody fusion device and, therefore, do not encompass aprevo™.

We have not identified an existing pass-through payment category that describes aprevo™. We are inviting public comment on whether aprevo™ meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. for the indication covered by the Breakthrough Device designation. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61295). Aprevo™ has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement. We note that the applicant was granted new technology add-on payments under the Alternative Pathway for Breakthrough Devices in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45132 through 45133).

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 aprevo™ would be reported with HCPCS codes in the following table.

TABLE 31: HCPCS Codes Reported with Aprevo™ Intervertebral Fusion Device

HCPCS Code	Long Descriptor	SI	APC
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)	N	N/A
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	J1	5116
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar	J1	5115

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5115, which had a CY 2021 payment rate of $12,314.76 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 22633 had a device offset amount of $6,851.93 at the time the application was received. According to the applicant, the cost of aprevo™ is $26,000.

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 $26,000 for aprevo™ is 211.13 percent of the applicable APC payment amount for the service related to the category of devices of $12,314.76 (($26,000/$12,314.76) × 100 = 211.13 percent). Therefore, we believe aprevo™ meets the first cost significance requirement.

The second cost significance requirement, 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 $26,000 for aprevo™ is 379.46 percent of the cost of the device-related portion of the APC payment amount for the related service of $6,851.93 (($26,000/$6,851.93) × 100 = 379.46 percent). Therefore, we believe aprevo™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $26,000 for aprevo™ and the portion of the APC payment amount for the device of $6,851.93 is 155.49 percent of the APC payment amount for the related service of $12,314.76 ((($26,000 − $6,851.93)/$12,314.76) × 100 = 155.49 percent). Therefore, we believe that aprevo™ meets the third cost significance requirement.

We are inviting public comment on whether aprevo™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) MicroTransponder® ViviStim® Paired Vagus Nerve Stimulation (VNS) System (Vivistim® System)

MicroTransponder, Inc. submitted an application for a new device category for transitional pass-through payment status for the ViviStim® Paired VNS System (Vivistim® System) for CY 2023. Per the applicant, the Vivistim® System is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

According to the applicant, the Vivistim® System is an active implantable medical device that is comprised of four main components: (1) an Implantable Pulse Generator (IPG), (2) an implantable Lead, (3) Stroke Application & Programming Software (SAPS), and (4) a Wireless Transmitter (WT). The IPG and Lead comprise the implantable components; the SAPS and WT comprise the non-implantable components.

The applicant asserts that the key feature of the biochemical process that underlies neural pathway development is called neuroplasticity. The applicant describes neuroplasticity as a complex biochemical process that is necessary for establishing new synaptic connections. The applicant further states it is widely understood that vagus nerve stimulation triggers the brain to release a burst of neuromodulators, such as acetylcholine and norepinephrine, which are enablers of neuroplasticity. In addition, the applicant further states it is understood that pairing neuromodulator bursts with events increases brain plasticity, which in turn increases the formation of new neural connections.[14] Per the applicant, the use of the external paired stimulation controller to precisely pair VNS with rehabilitation movements is essential to creating neuroplasticity in patients who have upper limb deficits, and this ''event-pairing'' of movement with VNS that generates long-lasting plasticity in the motor and sensory cortex leads to the restored motor function observed in clinical studies.[15]

The applicant specifies the SAPS and WT are non-implantable and are collectively called the External Paired Stimulation Controller. The applicant specifies the IPG and implantable Lead are implantable components. Per the applicant, the External Paired Stimulation Controller allow the implanted components (the IPG and Lead) to stimulate the vagus nerve while rehabilitation movement occurs through the following process: (1) The implantable Lead electrodes are attached to the left vagus nerve in the neck; (2) The implantable Lead is tunneled from the neck to the chest where it is connected to the IPG; (3) The IPG is placed subcutaneously (or sub-muscularly) in the pectoral region; (4) Following implantation of the IPG and stimulation Lead, the External Paired Stimulation Controller enables real-time ''event-pairing'' of vagus nerve stimulation and rehab movements; (5) The IPG and the implantable Lead stimulate the vagus nerve while rehabilitation movements occur; and (6) A therapist initiates the stimulation using a USB push-button or mouse click to synchronize the vagus nerve stimulation with rehabilitation movements to maximize the clinical effect. Patients undergo in-clinic rehabilitation, where vagus nerve stimulation is actively paired with rehabilitation by a therapist. Following in-clinic rehabilitation paired with vagus nerve stimulation, the patient can continue using the device at home. When directed by a physician, the patient can initiate at-home use by swiping a magnet over the IPG implant site which activates the IPG to deliver stimulation while rehabilitation movements are performed

With respect to the newness criterion at § 419.66(b)(1), Vivistim® System was granted FDA Breakthrough Device Designation effective February 10, 2021 for use in stimulating the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. The applicant states the Vivistim® System received FDA premarket approval (PMA) on August 27, 2021 as a Class III implantable device for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the Vivistim® System on September 1, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the Vivistim® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, VNS System is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) into the patient. We note that the external components SAPS and WT are not implanted in a patient and do not come in contact with the human tissue as required by § 419.66(b)(3). The applicant also claimed that VNS System 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. However, we note that the external non-implantable components SAPS and WT may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered and may be considered depreciable assets as described in § 419.66(b)(4). We are inviting public comments on whether VNS System

[14] Meyers EC, Solorzano BR, James J, Ganzer PD, Lai ES, Rennaker RL 2nd, Kilgard MP, Hays SA. Vagus Nerve Stimulation Enhances Stable Plasticity and Generalization of Stroke Recovery. Stroke. 2018 Mar;49(3):710–717.

[15] Hays SA, Rennaker RL, Kilgard MP. Targeting plasticity with vagus nerve stimulation to treat neurological disease. Prog Brain Res. 2013;207:275–299. doi:10.1016/B978–0–444–63327–9.00010–2.

meets the eligibility criteria at § 419.66(b).

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.

According to the applicant, there are several device categories that are similar to or related to the proposed device category. The applicant stated that there are five HCPCS device category codes describing neurostimulation devices that are similar to the Vivistim® System, listed in the following table below.

TABLE 32: HCPCS CODES REPORTED WITH THE VIVISTIM® SYSTEM

HCPCS Code	Long Descriptor	Status Indicator	APC
C1767	Generator, neurostimulator (implantable), non-rechargeable	N	N/A
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	N	N/A
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	N	N/A
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	H	2993
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	H	2030

Per the applicant, the codes in the table above do not encompass the Vivistim® System because none of the codes feature an external paired stimulation controller to actively pair stimulation with rehabilitation by a clinician, which is integral to the function and clinical benefit of the device, and the ViviStim® System does not include a rechargeable battery or charging system. The following paragraphs include the applicant's description of each related device category, the distinguishing device features and/or accessories of devices included in each of these categories, and the applicant's rationale for why the Vivistim® System device is not encompassed by these existing device categories.

Per the applicant, the Vivistim® System and similar device category codes that have preceded it (C1820, C1822, C1823, C1825) are distinct from the C1767 device category because of distinguishing device features and/or accessories not currently described by C1767.

The applicant stated that the C1767 was created in 2000 and was the first category for non-rechargeable neurostimulator generators. Per the applicant, the C1767 code currently describes multiple non-rechargeable neurostimulator generator devices that are approved to treat a wide variety of conditions. The applicant stated it is aware of currently marketed implantable, non-rechargeable vagus nerve stimulation devices, such as the VNS Therapy® System (LivaNova, PLC) which are described by C1767. Further, the applicant stated it is aware that CMS does not acknowledge indication for use alone as a reasonable basis to establish a new device category. According to the applicant, the VNS Therapy® System (LivaNova, PLC) has different device components and therapy delivery than the Vivistim® System. Per the applicant, the LivaNova VNS Therapy® System implantable neurostimulators differ from the Vivistim® System in a number of ways. Specifically, according to the applicant, VNS Therapy® System neurostimulators are ''always on'' and send periodic pulses to deliver therapy over the life of the device, whereas the Vivistim® System is actively paired with rehabilitation movements by a clinician to deliver therapy. In addition, the applicant stated the VNS Therapy® System is used to treat neurological disorders such as epilepsy and treatment resistant depression, whereas the Vivistim® System is used to treat upper limb motor deficits in ischemic stroke survivors. The applicant concluded C1767 does not encompass the Vivistim® System.

Per the applicant, C1820 describes an implantable neurostimulator that includes a rechargeable battery and charging system. The applicant stated it is aware of several marketed devices that are described by device category C1820 which was created in CY 2006. The applicant concluded C1820 does not encompass the Vivistim® System. Per the applicant, C1822 describes an implantable neurostimulator, which delivers ''high-frequency'' stimulation (10 kHz) and is provided with a rechargeable battery and charging system. The applicant stated it is aware of only one currently marketed device that is described by this device category, the HF10® Spinal Cord Stimulator (Nevro Corp.). The applicant stated the Vivistim® System is not a ''high-frequency'' stimulator as described by C1822. The applicant stated the paired stimulation using the Vivistim® System is delivered at a maximum of 30 Hz, whereas spinal cord stimulation using the HF10® (Nevro Corp.) is delivered at 10 kHz. The applicant concluded C1822 does not encompass the Vivistim® System.

According to the applicant, C1823 describes an implantable neurostimulator, which is nonrechargeable and includes transvenous sensing and stimulation leads. The applicant stated that it is aware of only one currently marketed device that is described by C1823, the remedē System® Phrenic Nerve Stimulator (Respicardia, Inc.). This device category code does not encompass the Vivistim® System. According to the applicant, the stimulation lead included in the Vivistim® System is placed onto the vagus nerve and is not transvenously placed to stimulate the phrenic nerve. In addition, the applicant asserted the Vivistim® System does not include a sensing lead. The applicant concluded C1823 does not encompass the Vivistim® System.

Per the applicant, C1825 describes an implantable neurostimulator which is nonrechargeable and includes a carotid sinus baroreceptor lead. The applicant stated it is aware of only one currently marketed device that is described by C1825, the BaroStim Neo™ (CVRx, Inc.). According to the applicant, the stimulation lead included in the ViviStim® System is placed onto the vagus nerve and is not placed on the carotid sinus. The applicant concluded C1825 does not encompass the Vivistim® System.

The applicant has asserted that the Vivistim® System is distinct from HCPCS codes C1820, C1822, C1823 and C1825 due to distinguishing features unique to these codes. These unique features include rechargeable batteries, high frequency stimulation, transvenous sensors and stimulators and unique placement of stimulators. With respect to C1767, however, the applicant's argument is that the Vivistim® System is not ''always on'' and is paired to an external stimulation controller to allow for clinician-controlled stimulation during rehabilitation, and therefore is unlike the non-rechargeable implantable neurostimulator of the VNS Therapy® System (LivaNova, PLC), which is described by C1767. It is our understanding, however, that implantable neurostimulators for epilepsy and depression are not ''always on'', but are programmed to turn on and off in specific cycles as determined by a clinician. Furthermore, in the case of treatment for epilepsy, a neurostimulator can be turned on by the patient with a hand held magnet if an impending seizure is sensed, and the neurostimulator can similarly be turned off by the patient during certain activities, such as speaking, exercising, or eating. As per the application, the IPG of the Vivistim® System can also be patient-engaged with a magnetic card, allowing the patient to continue therapy at home. In this context, we believe the Vivistim® System may be similar to the devices currently described by C1767, and therefore the Vivistim® System may also be appropriately described by C1767. We are inviting public comment on whether the Vivistim® System meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61295). The Vivistim® System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement. We note that the applicant has also submitted an application for IPPS New Technology Add-on payments for FY 2023 Payment under the Alternative Pathway for Breakthrough Devices (87 FR 28349 through 28350).

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 the insertion procedure for the Vivistim® System implantable pulse generator (IPG) and stimulation lead would be reported with the HCPCS Level I CPT code 64568 (Incision for implantation of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator).

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5465 Level 5 Neurostimulator and Related Procedures, which had a CY 2021 payment rate of $29,444.52 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 64568 had a device offset amount of $25,236.9 at the time the application was received. According to the applicant, the cost of the Vivistim® System is $36,000.00.

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 $36,000.00 for Vivistim® System is 122.26 percent of the applicable APC payment amount for the service related to the category of devices of $29,444.52 (($36,000.00/$29,444.52) × 100 = 122.26 percent). Therefore, we believe Vivistim® System meets the first cost significance requirement.

The second cost significance requirement, 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 $36,000.00 for Vivistim® System is 142.65 percent of the cost of the device-related portion of the APC payment amount for the related service of $25,236.90 (($36,000.00/$25,236.90) × 100 = 142.65 percent). Therefore, we believe that Vivistim® System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $36,000.00 for Vivistim® System and the portion of the APC payment amount for the device of $25,236.90 is 36.55 percent of the APC payment amount for the related service of $29,444.52 (($36,000.00 − $25,236.90)/$29,444.52) × 100 = 36.55 percent). Therefore, we believe that Vivistim® System meets the third cost significance requirement.

We are inviting public comment on whether Vivistim® System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

2. Traditional Device Pass-Through Applications

(1) The BrainScope TBI (Model: Ahead 500)

BrainScope Company Inc. submitted an application for a new device category for transitional pass-through payment status for the BrainScope Ahead 500 system (hereinafter referred to as the BrainScope TBI) for CY 2023. The BrainScope TBI is a handheld medical device and decision-support tool that uses artificial intelligence (AI) and machine learning technology to identify objective brain-activity based biomarkers of structural and functional brain injury in patients with suspected mild traumatic brain injury (mTBI). According to the applicant, the BrainScope TBI is an FDA-cleared, portable, non-invasive, point-of-care device and disposable headset intended to provide results and measures to aid in the rapid, objective, and accurate diagnosis of mTBI. Per the applicant, the BrainScope TBI is intended to be used in emergency departments (ED), urgent care centers, clinics, and other environments where used by trained medical professionals under the direction of a physician.

According to the applicant, the BrainScope TBI is comprised of two elements: (1) the Ahead 500, a disposable forehead-only 8-electrode headset temporarily applied to the patient's skin to assess brain injury (the wounded area) which records electroencephalogram (EEG) signals; and (2) a reusable handheld device (hereinafter ''Handheld Device''), which includes a standard commercial off-the-shelf handheld computer connected to a custom manufactured Data Acquisition Board (DAB) via a permanently attached cable. The applicant stated that the BrainScope software (including proprietary BrainScope algorithms) and a kiosk mode application running on Android are loaded onto an off-the-shelf handheld computer configuration. The disposable headset is attached to the DAB, which collects the EEG signal and passes it as a digital signal to the Handheld Device to perform the data processing and analysis.

According to the applicant, the BrainScope TBI device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (qEEG) parameters from frontal locations on a patient's forehead. Patient information is transferred to electronic health records via USB connected to a computer. The BrainScope TBI calculates and displays raw measures for the following standard qEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. The applicant asserts that these raw measures are intended to be used for post-hoc analysis of EEG signals for interpretation by a qualified user. Per the applicant, the device can be used as a screening tool and aid in determining the medical necessity of head computerized tomography (CT) scanning.

With respect to the newness criterion at § 419.66(b)(1), on September 11, 2019, the applicant received 510(k) clearance from FDA for the BrainScope TBI as a Class II device for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury, and have a Glasgow Coma Scale (GCS) score of 13–15 (including patients with concussion/mild traumatic brain injury (mTBI)). We received the application for a new device category for transitional pass-through payment status for the BrainScope TBI on February 23, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the BrainScope TBI meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the BrainScope TBI is integral to the service provided and is used for one patient only. Per the applicant, the Ahead 500 component records EEG signals via a disposable forehead-only 8-electrode headset and is temporarily applied to the patient's skin to assess brain injury. We note that while the Ahead 500 component is used for one patient only and it is temporarily applied to the patient's skin, the device is not surgically implanted or inserted or applied in or on a wound or other skin lesion, as required by 42 CFR 418.66(b)(3). We further note that the other component of the BrainScope TBI, the Handheld Device, does not come in contact with the patient's tissue, and the device is not surgically implanted or inserted or applied in or on a wound or other skin lesion, as required by § 418.66(b)(3). Per the applicant, the Handheld Device is used by multiple patients. We further question whether this device may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered in accordance with the device eligibility requirements of § 419.66(b)(4). The applicant did not indicate if the BrainScope TBI is a supply or material furnished incident to a service. We are inviting public comments on whether the BrainScope TBI meets the eligibility criteria at § 419.66(b).

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. The applicant has not identified any existing pass-through payment category that describes the BrainScope TBI. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to the BrainScope TBI. We are inviting public comment on whether the BrainScope TBI meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant indicated that it is aware of a marketed medical device COGNISION, which fits the proposed additional device category in addition to the BrainScope TBI. According to the applicant, the

COGNISION® System (COGNISION®) is cleared by FDA for use by qualified clinical professionals in private practice offices or small clinical settings for the acquisition, display, analysis, storage, reporting and management of EEG and auditory evoked potentials (AEP) information. The applicant stated that the COGNISION® cloud-powered electrophysiologic testing system evaluates patients with neurological disorders, such as dementia and concussion. According to the applicant, by measuring the electrical activity in the brain that is responsible for information processing, COGNISION® assesses cognitive function. The applicant also pointed out that COGNISION® evaluates working memory, focal attention, executive function, and brain processing speed through Event Related Potential (ERP) and qEEG tests. The applicant acknowledged that COGNISION® also measures hearing deficits which can be co-morbid with cognitive disorders.

The applicant stated that the BrainScope TBI represents a substantial clinical improvement over existing technology. With respect to this criterion, the applicant submitted studies that examined the impact of the BrainScope TBI as a brain injury adjunctive interpretive electroencephalograph assessment aid. Broadly, the applicant outlined the following areas in which it stated the BrainScope TBI would provide a substantial clinical improvement over existing technologies: (1) decreased rate of repeat/subsequent diagnostic or therapeutic interventions, (2) more rapid beneficial resolution of the disease process treated because of the use of the device, and (3) reduced recovery time when used for the treatment mild head injuries (mTBI).

In support of its first claim that the BrainScope TBI decreases the rate of subsequent diagnostic or therapeutic interventions, the applicant provided five articles. The first was a multisite, prospective observational FDA validation trial performed in the U.S.[16] A total of 720 patients (18–85 years) meeting inclusion/exclusion criteria were enrolled at 11 U.S. EDs. Ninety-seven percent of study participants had a Glasgow Coma Scale (GCS) of 15, with the first and third quartiles being 15 (interquartile range = 0) at the time of the evaluation. Standard clinical evaluations were conducted, and 5 to 10 minutes of EEG was acquired from frontal and frontotemporal scalp locations. Using an a priori derived EEG-based classification algorithm developed on an independent population and applied to this validation population prospectively, the likelihood of each subject being CT+ was determined, and performance metrics were computed relative to adjudicated CT findings. The authors stated that by using an EEG-based biomarker, high accuracy of predicting the likelihood of being CT+ was obtained, with high normalized power variance (NPV) and sensitivity to any traumatic bleeding and to hematomas. Per the authors, specificity was significantly higher than standard CT decision rules and the short time to acquire results and the ease of use in the ED environment suggests that EEG-based classifier algorithms have potential to impact triage and clinical management of head-injured patients. Both the applicant and the authors indicated that the BrainScope TBI Structural Injury Classifier (SIC)[17] biomarker demonstrated extremely high sensitivity in this validation study. Sensitivity for those who are CT+ with ≥1mL blood was 98.6 percent (72/73, 95% CI = 92.6%–100.0 percent), with an area under the curve (AUC) of 0.82. It is noted that this study could not be run as a randomized controlled trial (RCT) as the individual site institutional review boards (IRBs) would not allow random assignment to determination to receive a CT, which was entirely at the discretion of the clinician. Results supported the potential to impact triage and clinical management and help in avoidance of unnecessary CT scans. High NPV supports confidence added to decisions not to perform a CT scan. In this validation study, the BrainScope TBI's SIC biomarker reported 2% false negatives (FNs), none of which were considered by clinical sites or FDA to be ''clinically important,'' and all of which were confirmed in follow-up as requiring no further care. In the same large FDA prospective validation study, the BrainScope's SIC biomarker had specificity of 51.60 percent (291/564, 95 percent CI = 48.05 percent–55.13 percent). In the same population, SIC specificity outperformed that of the standard clinical CT decision rules, with the New Orleans Criteria (NOC) = 8.6 percent and Canadian CT Head Rule (CCHR) = 31 percent. Higher specificity relative to standard practice supports reduced CT referrals. In the same large FDA prospective validation study specificity of the BrainScope TBI's SIC biomarker was shown to scale with severity of clinical functional impairment, with specificities of 76.7 percent, 58.8 percent, and 22.2 percent for none, mild, and moderate functional impairment, respectively.

The second article was a retrospective secondary study of the independent prospective FDA validation trial that demonstrated the efficacy of (1) an automatic SIC for the likelihood of injury visible on a CT (CT+) and (2) an EEG-based Brain Function Index (BFI) to assess functional impairment in minimally impaired, head-injured adults presenting within 3 days of injury.[18] In this retrospective analysis, the impact on the biomarker performance in patients who presented with or without drug and alcohol (DA) was studied. DA–ED visits represent an increasing fraction of the head-injured population seen in the ED. Such patients present a challenge to the evaluation of head injury and determination of need for CT scan and further clinical pathways. This effort examined whether an EEG-based biomarker could aid in reducing unnecessary CT scans in the intoxicated ED population. SIC sensitivity was not significantly impacted by the presence of DA. Although specificity decreased, it remained several times higher than obtained using standard CT decision rules. Furthermore, according to the authors, the potential to reduce the number of unnecessary scans by approximately 30% was demonstrated when the BrainScope TBI SIC was integrated into CT clinical triage. According to the authors, the BFI was demonstrated to be independent of the presence of DA.

The third article was a retrospective clinical study conducted in the U.S.[19] Two potential initial evaluation pathways were compared for CT referrals: a. Clinical Site Practice Referral, relying on clinical judgement of the ED physician according to site standard of care; and b. EEG-based

[16] Hanley D, Prichep LS, Bazarian J, Huff JS, Naunheim R, Garrett J, Jones EB, Wright DW, O'Neill J, Badjatia N, Gandhi D. Emergency department triage of traumatic head injury using a brain electrical activity biomarker: a multisite prospective observational validation trial. Academic emergency medicine. 2017 May;24(5):617–27.

[17] The SIC is an electrophysiological based biomarker derived from selected EEG features and a small set of clinical associated symptoms, using machine learning and advanced classification algorithms to identify those features which optimally characterize the pattern of changes in brain function that occur with head injury.

[18] Michelson, E., Huff, J.S., Garrett, J., & Naunheim, R. (2019). Triage of mild head-injured intoxicated patients could be aided by use of an electroencephalogram-based biomarker. Journal of neuroscience nursing, 51(2), 62–66.

[19] Naunheim, R., Koscso, M. K., & Poirier, R. (2019). Reduction in unnecessary CT scans for head-injury in the emergency department using an FDA cleared device. The American journal of emergency medicine, 37(10), 1987–1988.

classification algorithm assessment, relying on the ternary output of the SIC (positive, negative, equivocal) to inform CT referral decision. The SIC is an electrophysiological based biomarker derived from selected EEG features and a small set of clinical associated symptoms, using machine learning and advanced classification algorithms to identify those features which optimally characterize the pattern of changes in brain function that occur with head injury. Of the 91 patients referred to CT, 13 were read as positive and 78 as negative. These 91 CT referrals made using the clinical judgement decision pathway resulted in 78 patients who were found to be CT negative. Using the second pathway with input from the EEG based classification algorithm assessment (SIC) resulted in 63 patients who were positive for CT referral. Thus, the researchers stated that the use of the EEG-based algorithm decision pathway to aid in referral for CT scanning would have resulted in 63 patients being referred for CT scans instead of 91 referrals made following standard clinical site practice. Per the researchers, this represents a reduction of 28 fewer head CT scans, a 30.8 percent (= (91 − 63)/91) reduction. According to the researchers, while still early in the clinical use of this EEG based biomarker, this data demonstrates that the BrainScope TBI medical device can provide objective information to aid in the initial assessment of mTBI patients in the ED. The researchers suggested that integrating this data into the decision-making process for CT referrals would have led to a significant reduction of ~31 percent in CT scanning. The researchers concluded that this decrease in CT use and its associated radiation was achieved without incurring any false negative cases (100 percent sensitivity).

The fourth article was a retrospective clinical study conducted in the U.S.[20] The study authors found that heightened awareness of the potential short and long-term consequences of mild traumatic brain injury (mTBI or concussion) has resulted in an increase in ED visits for traumatic head injury, even as the volume of overall ED visits has remained stable over the same period of time.[21] While the vast majority (~95%) of these head injured patients are mild, >80% receive CT scans of which ~91% are found to be negative.[22] The rising number of negative CT findings, cost, radiation exposure, and ED resource utilization, has led to an increased need for reliable predictors of intracranial injury in the mild head injured population.[23] Based on a retrospective analysis of data collected in the BrainScope's multisite independent FDA validation study, it was found that had the SIC been used in determination as an input for CT scan referral, there would have been a reduction of false positives of 33.3% (408272/408). In addition, according to the study, a significantly lower false discovery rate of 65% (= 272/416) was achieved compared to the clinical site practice (one-sided comparison, p = 0.01).

The fifth article was a retrospective clinical study conducted in the U.S.[24] This study compares the predictive power using that algorithm (which includes loss of consciousness (LOC) and amnesia), to the predictive power of LOC alone or LOC plus traumatic amnesia. Study participants consisted of ED patients 18–85 years who presented within 72 hours of closed head injury, with Glasgow Coma Scale (GCS) between 12–15. 680 patients with known absence or presence of LOC were enrolled (145 CT + and 535 CT − patients). 5–10 min of eyes closed EEG was acquired using the Ahead 300 handheld device, from frontal and frontotemporal regions. The same classification algorithm methodology was used for both the EEG-based and the LOC-based algorithms. Predictive power was evaluated using area under the receiver operator characteristic (ROC) curve (AUC) and odds ratios. The Quantitative EEG-based classification algorithm demonstrated significant improvement in predictive power compared with LOC alone, both in improved AUC (83% improvement) and odds ratio (increase from 4.65 to 16.22). Adding retrograde amnesia (RGA) and/or post-traumatic amnesia (PTA) to LOC was not improved over LOC alone. The AUC for LOC only predictive method was 0.68, and for LOC +RGA/PTA was 0.69. The AUC for the BrainScope structural injury classifier is 0.83, which represents an 83% improvement over the standard clinical predictors (LOC and/or RGA). Rapid triage of TBI relies on strong initial predictors. The authors concluded that the addition of an electrophysiological based marker was shown to outperform report of LOC alone or LOC plus amnesia, in determining risk of an intracranial bleed. In addition, according to the authors, ease of use at point-of-care, non-invasive, and rapid result using such technology suggests significant value added to standard clinical prediction.

With respect to the claim that the BrainScope TBI provides for a more rapid, beneficial resolution of the disease process treated, the applicant provided a consensus modeling retrospective clinical study conducted in the U.S.[25] The study researchers developed a care map that included each step of evaluation of mTBI (Glasgow Coma Scale Score 13–15), from initial presentation to the ED to discharge. Time spent at each step was estimated by study-affiliated emergency physicians and nurses. The study subsequently validated time estimates using retrospectively collected, real-time data at two EDs. Length of stay (LOS) time differences between admission and discharged patients were calculated for patients being evaluated for mTBI. Evaluation of time from ED intake to discharge in a mTBI population was modeled by a medical consensus group and validated in retrospective review of real-time data. Mean time was 6.6 hours. Time related to head CT comprised about one-half of the total LOS. The authors concluded that limiting use of head CT as part of the workup of mTBI to more serious cases may reduce time spent in the ED and potentially improve overall ED throughput.

To support the claim of a decreased rate of subsequent diagnostic or therapeutic interventions and reduced recovery time using the device, the applicant provided a retrospective clinical pilot study conducted in the U.S.[26] that focused on the immediate use and implementation of the BrainScope TBI in the ED environment for the triage of 19 head-injured

[20] Huff, J.S., Naunheim, R., Dastidar, S.G., Bazarian, J., & Michelson, E.A. (2017). Referrals for CT scans in mild TBI patients can be aided by the use of a brain electrical activity biomarker. The American Journal of Emergency Medicine, 35(11), 1777–1779.

[21] Marin, J.R., Weaver, M.D., Yealy, D.M., & Mannix, R.C. (2014). Trends in visits for traumatic brain injury to emergency departments in the United States. Jama, 311(18), 1917–1919.

[22] Korley, F.K., Kelen, G.D., Jones, C.M., & Diaz-Arrastia, R. (2016). Emergency department evaluation of traumatic brain injury in the United States, 2009–2010. The Journal of head trauma rehabilitation, 31(6), 379.

[23] American College of Emergency Physicians. (2015). ACEP Announces List of Tests as Part of Choosing Wisely Campaign.

[24] Hack, D., Huff, J.S., Curley, K., Naunheim, R., Dastidar, S.G., & Prichep, L.S. (2017). Increased prognostic accuracy of TBI when a brain electrical activity biomarker is added to loss of consciousness (LOC). The American Journal of Emergency Medicine, 35(7), 949–952.

[25] Michelson, E.A., Huff, J.S., Loparo, M., Naunheim, R.S., Perron, A., Rahm, M., & Berger, A. (2018). Emergency department time course for mild traumatic brain injury workup. Western Journal of Emergency Medicine, 19(4), 635.

[26] Clay, M.S. Clinical Utility of an EEG Based Biomarker for the Triage of Head Injured Patients in the ED: INOVA Pilot Study.

patients: ages 18 to 85, GCS 13–15, within 72 hours of injury, from April 26th to May 1, 2021. According to this study, the results reinforced the clinical utility of the BrainScope technology to be a reliable tool for clinicians to proactively catch injuries that may not have been sent for CT and to reduce unnecessary CT's, thus reducing LOS. The author indicated that the BrainScope TBI was an effective decision-making aide in determining the appropriate use of imaging for closed head injuries. The author stated that within one rapid EEG test at the point of care, the BrainScope provided objective data on both brain bleeds and concussions to assist healthcare providers evaluate head injured patients. According to the author, this study was successful in determining utilization, staff assessment, and patient experience of the BrainScope technology in daily use. The author noted the results of the trial were positive and demonstrated the following: (1) 100 percent patient satisfaction with BrainScope; (2) Improved CT utilization in the mild TBI patient population: 60 percent reduction in head CT. Decreased radiation exposure. One patient was sent for CT after receiving a positive result from BrainScope TBI SIC that was found CT positive and who may not have been sent otherwise; and (3) Decreased LOS for patients who were BrainScope negative for structural injury. An average of 16-minute testing times had a positive impact on LOS for patients who were BrainScope negative.

In support of the claim that the BrainScope TBI reduces recovery time, the applicant submitted four articles. The first was a prospective clinical study conducted in the U.S.[27] The potential clinical utility of a quantitative EEG-based BFI as a measure of the presence and severity of functional brain injury was studied as part of an independent prospective validation trial. The BFI was derived using qEEG features associated with functional brain impairment reflecting current consensus on the physiology of concussive injury. The applicant asserted that the results supported FDA clearance for the BFI as a quantitative marker of brain function impairment. Per the applicant, a multinomial logistic regression analysis demonstrated odds ratios (versus controls) of the mild and moderate functionally impaired groups were significantly different from the odds ratio of the severe group (CT+), (p=0.0009, p=0.0026, respectively). Per the applicant, regression slopes for likelihood of group membership demonstrated that BFI scaled with severity of impairment contributed to earlier identification and intervention of concussion, which is associated with better outcomes.

Another article provided by the applicant to support the claim of reduced recovery time associated with the use of the BrainScope TBI, was a multisite prospective observational validation trial conducted in the U.S.[28] The study was to validate the classification accuracy of a previously derived, machine learning, multimodal, brain electrical activity–based Concussion Index (CI) in an independent cohort of athletes with concussion. This prospective diagnostic cohort study was conducted at 10 clinical sites (*i.e.,* U.S. universities and high schools) between February 4, 2017 and March 20, 2019. A cohort comprised of a consecutive sample of 207 athletes aged 13 to 25 years with concussion and 373 matched athlete controls without concussion were assessed with electroencephalography, cognitive testing, and symptom inventories within 72 hours of injury, at return to play, and 45 days after return to play. Variables from the multimodal assessment were used to generate a Concussion Index at each time point. Athletes with concussion had experienced a witnessed head impact, were removed from play for 5 days or more, and had an initial Glasgow Coma Scale score of 13 to 15. Participants were excluded for known neurologic disease or history within the last year of traumatic brain injury. Athlete controls were matched to athletes with concussion for age, sex, and type of sport played. Classification accuracy of the CI at time of injury using a prespecified cutoff of 70 or less (total range, 0–100, where ≤70 indicates it is likely the individual has a concussion and >70 indicates it is likely the individual does not have a concussion). Results included 580 eligible participants with analyzable data, of whom 207 had concussion (124 male participants [59.9 percent]; mean [standard deviation (SD)] age, 19.4 [2.5] years), and 373 were athlete controls (187 male participants [50.1 percent]; mean [SD] age, 19.6 [2.2] years). The CI had a sensitivity of 86.0 percent (95 percent CI, 80.5 percent–90.4 percent), specificity of 70.8 percent (95 percent CI, 65.9 percent–75.4 percent), negative predictive value of 90.1 percent (95 percent CI, 86.1 percent–93.3 percent), positive predictive value of 62.0 percent (95 percent CI, 56.1 percent–67.7 percent), and area under receiver operator characteristic (ROC) curve of 0.89. At day 0, the mean [SD] CI among athletes with concussion was significantly lower than among athletes without concussion (75.0 [14.0] vs 32.7 [27.2]; P <.001). The researchers noted that among athletes with concussion, there was a significant increase in the CI between day 0 and return to play, with a mean (SD) paired difference between these time points of −41.2 (27.0) (P <.001). The researchers concluded that these results suggest that the multimodal brain activity–based CI has high classification accuracy for identification of the likelihood of concussion at time of injury and may be associated with the return to control values at the time of recovery. According to the researchers, the CI has the potential to aid in the clinical diagnosis of concussion and in the assessment of athletes' readiness to return to play.

The final article provided by the applicant in support of the claim of reduced recovery time was a multisite prospective observational validation trial conducted in the U.S.[29] This study was to derive an objective multimodal CI using EEG at its core, to identify concussion, and to assess change over time throughout recovery. Male and female concussed (n = 232) and control (n = 206) subjects 13–25 years were enrolled at 12 U.S. colleges and high schools. Evaluations occurred within 72 hours of injury, 5 days post-injury, at return-to-play (RTP), 45 days after RTP (RTP + 45); and included EEG, neurocognitive performance, and standard concussion assessments. Concussed subjects had a witnessed head impact, were removed from play for ≥5 days using site guidelines and were divided into those with RTP <14 or ≥14 days. Part 1 of this paper described the derivation and efficacy of the machine learning derived classifier as a marker of concussion. Part 2 of this paper described significance of

[27] Hanley D, Prichep LS, Badjatia N, Bazarian J, Chiacchierini R, Curley KC, Garrett J, Jones E, Naunheim R, O'Neil B, O'Neill J, Wright DW, Huff JS. A Brain Electrical Activity Electroencephalographic-Based Biomarker of Functional Impairment in Traumatic Brain Injury: A Multi-Site Validation Trial. J Neurotrauma. 2018 Jan 1;35(1):41–47. doi: 10.1089/neu.2017.5004. Epub 2017 Sep 21. PMID: 28599608.

[28] Bazarian, J.J., Elbin, R.J., Casa, D.J., Hotz, G.A., Neville, C., Lopez, R.M., . . . & Covassin, T. (2021). Validation of a machine learning brain electrical activity–based index to aid in diagnosing concussion among athletes. JAMA network open, 4(2), e2037349–e2037349.

[29] Jacquin AE, Bazarian JJ, Casa DJ, Elbin RJ, Hotz G, Schnyer DM, Yeargin S, Prichep LS, and Covassin T. Concussion assessment potentially aided by use of an objective multimodal concussion index. Journal of Concussion. January 2021. doi:10.1177/20597002211004333.

differences in CI between groups at each time point and within each group across time points. Per the researchers, the CI was shown to have high accuracy as a marker of likelihood of concussion and stability of CI in controls supports reliable interpretation of CI change in concussed subjects. The researchers concluded that the objective identification of the presence of concussion and assessment of readiness to return to normal activity can be aided by use of the CI, a rapidly obtained, point of care assessment tool. Sensitivity = 84.9 percent, specificity = 76.0 percent, and AUC = 0.89 were obtained on a test Hold-Out group representing 20 percent of the total dataset. Per the study, EEG features reflecting connectivity between brain regions contributed most to the CI. CI was stable over time in controls. According to the researchers, significant differences in CI between controls and concussed subjects were found at time of injury, with no significant differences at RTP and RTP + 45. Within the concussed, the researchers were able to identify differences in rate of recovery.

Based on the evidence submitted with the application, we note the following concerns. We note that most articles and citations provided by BrainScope are prospective observational studies or retrospective review articles, and most findings appear to be suggestive, rather than conclusive, of an association or significant benefit. Within the retrospective and prospective studies lacking a control subset, we note that some level of selection bias may potentially influence outcomes seen in these studies. Further, we note that confounding often occurs in both prospective and retrospective studies, which may result in misinterpretation of the observed relationships between the dependent and independent values. In most of the studies, the authors did not address potential confounding issues, which makes it difficult to determine whether the BrainScope TBI or the control was effective with its results.

We further note that the applicant provided retrospective clinical validation studies,[30] [31] which describe findings for previous BrainScope technology, the BrainScope Ahead 300 handheld device, not the nominated BrainScope Ahead 500 handheld device. Per the applicant, the BrainScope Ahead 500 improves upon the prior versions of BrainScope's own previously FDA-cleared devices. The applicant does not provide comparative outcome data between the current and previous versions. Additional information regarding comparative outcomes data would help inform our assessment of whether the BrainScope TBI Ahead 500 demonstrates a substantial clinical improvement over existing technologies, including the BrainScope Ahead 300. We note concern that even though the applicant states that it is a prospective trial the paper was noted to be a retrospective secondary study of an independent study by FDA.

Lastly, we note that the cited studies have a small sample size. In addition, conclusions in the application regarding the referenced observational and retrospective studies about substantial clinical improvement appear to be overly broad and imply statistical significance, when only a possible association may in fact be supported. We further note that the majority of the studies lacked a comparator to the existing technologies that the applicant identified when assessing the effectiveness of the BrainScope TBI. In addition, the applicant identified the COGNISION® System as an existing device, but we did not receive any citations or supporting references regarding comparability of these technologies. We also note that there are two additional FDA-cleared, potential alternate therapies [32] [33] that could be relevant, but the applicant did not provide citations or supporting references regarding comparability specifically in the application. Additional information regarding comparative outcomes data would help inform our assessment of whether the BrainScope TBI demonstrates a significant clinical improvement over existing technologies.

We are inviting public comments on whether the BrainScope TBI 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 BrainScope TBI would be reported with HCPCS codes listed in the following table:

[30] Hack, D., Huff, J.S., Curley, K., Naunheim, R., Dastidar, S.G., & Prichep, L.S. (2017). Increased prognostic accuracy of TBI when a brain electrical activity biomarker is added to loss of consciousness (LOC). The American Journal of Emergency Medicine, 35(7), 949–952.

[31] Hanley D, Prichep LS, Bazarian J, Huff JS, Naunheim R, Garrett J, Jones EB, Wright DW, O'Neill J, Badjatia N, Gandhi D. Emergency department triage of traumatic head injury using a brain electrical activity biomarker: a multisite prospective observational validation trial. Academic emergency medicine. 2017 May;24(5):617–27.

[32] *https://abbott.mediaroom.com/2021-01-11-Abbott-Receives-FDA-510-k-Clearance-for-the-First-Rapid-Handheld-Blood-Test-for-Concussions.*

[33] *https://www.mobihealthnews.com/news/syncthink-scores-fda-clearance-ai-system-aid-concussion-diagnosis.*

TABLE 33: HCPCS CODES REPORTED WITH THE BRAINSCOPE TBI

HCPCS Code	Long Descriptor	Status Indicator	APC
95816	Electroencephalogram (eeg); including recording awake and drowsy	S	5722
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	Q3	5722
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes	Q3	5734
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes	Q3	5735
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only	Q3	5731

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5731—Level 1 Minor Procedures, which had a CY 2021 payment rate of $24.67 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). However, we note that all the HCPCS codes identified by the applicant had a device offset amount of $0.00 at the time the application was received, including the HCPCS code 96146. Accordingly, we are evaluating the cost significance requirements consistent with how we previously have treated other items with a device offset amount of $0.00 (see 84 FR 61285). According to the applicant, the cost of BrainScope TBI (single use disposable electrode headset) is $225.00.

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 $225.00 for BrainScope TBI is 912.04 percent of the applicable APC payment amount for the service related to the category of devices of $24.67 (($225/$24.67) × 100 = 912.04 percent). Therefore, we believe BrainScope TBI meets the first cost significance requirement.

The second cost significance requirement, 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). Given that there are no device-related costs in the APC payment amount, and the BrainScope TBI has an estimated average reasonable cost of $225, we believe that the BrainScope TBI meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $225 for BrainScope TBI and the portion of the APC payment amount for the device of $0.00 exceeds the APC payment amount for the related service of $225 by 912.04 percent ((($225 − $0.00)/$24.67) × 100 = 912.04 percent). Therefore, we believe that the BrainScope TBI meets the third cost significance requirement.

We are inviting public comment on whether the BrainScope TBI meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) NavSlim™ and NavPencil

Elucent Medical, Inc. submitted an application for a new device category

for transitional pass-through payment status for CY 2023 for the NavSlim™ and NavPencil (referred to collectively as ''the Navigators''). The applicant described the Navigators as single-use (disposable) devices for real-time, stereotactic, 3D navigation for the excision of pre-defined soft tissue specimens.

According to the FDA 510(k) Summary (K183400) provided by the applicant,[34] the Navigators are a component of the applicant's EnVisio™ Navigation System [35] which is intended only for the non-imaging detection and localization (by navigation) of a SmartClip™ Soft Tissue Marker (SmartClip™) that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.[36] We note that the applicant submitted a separate application for pass-through payment status for the SmartClip™ for CY 2023, as discussed in a subsequent section. The applicant explained that the sterile, single-use Navigators affix to an electrocautery (surgical cutting) tool and, in combination with the other EnVisio™ Navigation System components and the SmartClip™, provide real-time intraoperative 3D navigation to the tumor and margin. The applicant explained that, at the time of surgical intervention, electromagnetic waves delivered by the EnVisio™ Navigation System activate the implanted SmartClip™ within a 50cm × 50cm × 35cm volume. The applicant further explained that the SmartClip™ contains an application-specific integrated circuit (ASIC) which is activated at a specific frequency and communicates to the EnVisio™ Navigation System the precise, real-time location of both the SmartClip™ and the surgical margin, enabling the surgeon to plan the specimen (tumor and margin) for excision. The applicant asserted that this data is calibrated relative to the tip of the electrocautery device or other operating instrument and is displayed in 3D. According to the applicant, the Navigators enable intraoperative visualization by displaying real-time stereotactic 3D guidance from the tip of the surgical tool enabling minimally invasive removal of pre-defined tissue specimen (tumor and margin). The applicant stated that surgeons are able to visualize the directional distances to make excisional plane of each margin in-situ without using conventional imaging (*e.g.,* ultrasound).

The applicant stated that there are two types of Navigators: (1) the NavSlim™ (which the applicant described as a lightweight model that allows integration with a broader range of electrosurgical tools, with or without smoke evacuation); and (2) the NavPencil (which, according to the applicant, incorporates a small screen in the surgical sightline that mimics the EnVisio™ Navigation System operating room monitor). The applicant also asserted that the integration of the Navigators with the single use, sterile electrocautery tool enables a single, light weight tool that can be utilized in situ for a minimally invasive surgery without infection risk. According to the applicant, the Navigators reduce the risk of tumor microenvironment caused by tissue disruption of non-targeted tissue. The applicant stated that the patient populations that can benefit from this technology are those that have biopsy proven cancers in organs that lack anatomic landmarks like breast, abdomen, and head and neck.

The applicant stated that the Navigators are the first devices to provide precise real-time navigation with a large patient volume of 50cm × 50cm × 35cm (per the applicant, encompassing >99 percent of breast cancer patient habitus and >90 percent of lung cancer patient habitus). In addition, the applicant asserted several other clinically differentiating features from prior products. First, the applicant stated that the Navigators process 240 simultaneous data streams solving for location 16 times per second with millimeter level of accuracy, and display it to the surgeon based upon actual location of the defined lesion as it is manipulated in situ, not based on imaging that occurred days or weeks before. The applicant asserted that as the tissue is moved or manipulated during a surgical intervention, the location is instantaneously updated. According to the applicant, this allows for intelligent, real-time, intraoperative visualization and guidance for the surgeon, enabling precise removal of a defined tissue specimen (including tumor and margin). Furthermore, the applicant asserted that the accurate and real-time wireless location eliminates any potential registration errors that are typically found in devices that use pre-procedure imaging for guidance. The applicant explained that no static pre-procedure imaging is necessary eliminating the potential of mis-registration due to patient or tissue movement. In addition, the applicant stated that the Navigators provide 3D guidance—medial/lateral, inferior/superior and anterior/posterior, as well as the most direct path, and asserted that this is increasingly important in treating lobular and deep tumors. The applicant also claimed that because the guidance is from the tip of the cutting tool, exact measurements can be taken in situ at the exact cutting location. In addition, per the applicant, the Navigators allow for an oncoplastic [37] approach—the applicant stated that because the location is not tethered or constrained in any way, the surgeon can choose the best cutting approach to achieve the optimal oncoplastic outcome. Finally, the applicant added that the Navigators provide the ability to distinctly identify and navigate up to three separate lesions in the same patient.

With respect to the newness criterion at § 419.66(b)(1), on March 22, 2019, the applicant received 510(k) clearance from FDA to market the EnVisio™ Navigation System (which, as explained previously, includes the Navigators) for the non-imaging detection and localization (by navigation) of a SmartClip™ that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Navigators on February 28, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Navigators meet the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Navigators are an integral part of the service furnished and are used for one patient only. However, the applicant did not specifically indicate whether the Navigators come in contact with human tissue, and are surgically implanted or inserted or applied in or on a wound or other skin lesion, as

[34] As explained later in this section, the applicant received FDA 510(k) clearance for the EnVisio™ Navigation System, which includes the Navigators.

[35] The FDA 510(k) Summary for the EnVisio™ Navigation System states that the EnVisio™ Navigation System ''equipment components'' are the Console, Heads Up Display, Patient Pad and Foot Pedal. The Navigator is listed as a separate, sterile, non-patient contacting, single-use system component. The applicant submitted an application for pass-through payment status only for the Navigator component of the EnVisio™ Navigation System.

[36] The SmartClip™ has a separate FDA 510(k) clearance. Based on the FDA 510(k) Summary for the EnVisio™ Navigation System, the SmartClip™ does not appear to be part of the EnVisio™ Navigation System.

[37] According to Columbia University Irving Medical Center, oncoplastic breast surgery combines the techniques of traditional breast cancer surgery with the cosmetic advantages of plastic surgery. *https://columbiasurgery.org/conditions-and-treatments/oncoplastic-breast-surgery.*

required at § 419.66(b)(3).[38] The FDA 510(k) Summary (K183400) states that the Navigator is a sterile, non-patient contacting, single-use device. We would welcome comments on whether the Navigators meet the requirements of § 419.66(b)(3). The applicant also did not indicate whether the Navigators meet the device eligibility requirements at § 419.66(b)(4), which provide that the device may not be any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker). We are inviting public comments on whether the Navigators meet the eligibility criteria at § 419.66(b).

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. The applicant stated that it was not aware of an existing pass-through payment category that describes the Navigators, and listed an existing device category that it considered for comparison to the Navigators—specifically, HCPCS code C1748 (Endoscope, single-use (*i.e.,* disposable), upper GI, imaging/illumination device (insertable)). The applicant stated that the Navigators are designed to meet the demands within the clinical environment for a single-use (*i.e.,* disposable) device to decrease infection rate, similar to the recent advancements of ''disposable'' endoscopes to address clinical demands for single-use to eliminate risks of cross contamination and improper sterilization. HCPCS code C1748 is a current pass-through payment category, effective beginning July 1, 2020. The applicant did not specifically differentiate the Navigators from devices in HCPCS code C1748. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to the Navigators. We are inviting public comments on whether the Navigators meet the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that the use of the Navigators results in substantial clinical improvement over existing technologies by (1) reducing positive margin and re-excision rates, thereby decreasing the rate of subsequent therapeutic interventions; (2) reducing the rate of device-related complications, including surgical site infections and wire migration and transection; and (3) improving the surgical approach (surgeons are not tethered to the best radiological approach, and the incision can be placed in the ideal location resulting in better oncoplastic results, less complex path to the lesion, and better visualization during surgery). The applicant provided articles and case reports for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that use of the Navigators reduces positive margin and re-excision rates, the applicant submitted an abstract of a study performed to assess the impact of electromagnetic seed localization (ESL) using the EnVisio™ Navigation System and SmartClip™ compared to wire localization (WL) on operative times, specimen volumes, margin positivity, and margin re-excision rates.[39] Between August 2020 and August 2021, 97 patients underwent excisional biopsy (n=20), or lumpectomy with (n=53) or without (n=24) sentinel lymph node biopsy (SLNB) using ESL guidance at a single institution by 5 surgeons. The study authors matched these patients, one-to-one, with WL patients undergoing surgery between 2006 and 2021 based on surgeon, procedure type with stratification for those having and not having nodal procedures, and pathologic stage or benign pathology. When greater than one WL match was found, selection was randomized. The authors compared continuous variables (operative times, specimen volumes, excess volume excised) between patients undergoing ESL and WL using Wilcoxon rank sums tests. The authors compared categorical variables (positive margin rates, re-excision rates) using Fisher's exact tests. Median operative time for ESL versus WL for lumpectomy with SLNB was 66 versus 69 minutes (p=0.76) and without SLNB was 40 versus 34.5 minutes (p=0.17). Median specimen volume was 55cm^3 with WL versus 36cm^3 with ESL (p=0.0012). In those with measurable tumor volume, excess tissue excised was larger with WL compared to ESL (median=73.2cm^3 versus 52.5cm^3, p=0.017). Main segment margins were positive in 18 of 97 (19 percent) WL patients compared to 10 of 97 (10 percent) ESL patients (p=0.17). In the WL group, 13 of 97 (13 percent) had margin re-excision at a separate procedure, compared to 6 of 97 (6 percent) in the ESL group, (p=0.15). The authors concluded that ESL is superior to WL because it provided more accurate localization, evidenced by smaller specimen volume with less excess tissue excised, despite similar operative times. In addition, the authors reported that, although not statistically significant, ESL resulted in lower positive margin rates and lower margin re-excision rates compared to WL. The authors further noted that ESL allows for preoperative localization, eliminating same day operative delays, and single tool 3D localization. The authors concluded that further studies comparing ESL to other non-wire localization techniques are required to refine which localization technology is most advantageous in breast conservation surgery.

The applicant provided a second article consisting of a clinical paper from the Moffitt Cancer Center that, per the applicant, is pending publication.[40] The paper presented three cases from the Moffitt Cancer Center, including radiographic and other images, employing three different methods of breast mass localization: (1) SmartClip™, (2) SAVI SCOUT® radar reflector localizer, and (3) traditional wire localizer. The authors stated that the purpose of the paper was to educate

[38] By contrast, the SmartClip™, discussed in the next section of this preamble, is inserted into human tissue.

[39] Jordan R, Rivera-Sanchez L, Kelley K, O'Brien M, et al. The Impact of an Electromagnetic Seed Localization Device as Versus Wire Localization on Breast Conserving Surgery: A Matched Pair Analysis. Abstract presented at: 23rd Annual Meeting of The American Society of Breast Surgeons; April 6–10, 2022. *https://www.breastsurgeons.org/meeting/2022/docs/2022_Official_Proceedings_ASBrS.pdf.*

[40] Ibanez J, Wotherspoon T, Mooney B, Advances in Image Guided Breast Mass Localization Techniques (undated). Submitted by the applicant with its application on February 28, 2022.

the audience about the technological advances regarding breast mass localization and to discuss the advantages and disadvantages of SmartClip™ localizers, SAVI SCOUT® localizers, and wire localizers.

The authors first discussed wire localization, stating that wire localization involves image-guided insertion of a guidewire into a targeted mass and that the use of multiple wires allows for bracketing of multiple lesions or a large lesion. The authors asserted that, while effective in localization, this procedure has drawbacks such as wire breakage, patient discomfort, wire migration while moving or transporting the patient, and the need to surgically remove the wire the same day that it is placed due to this risk of migration.

The authors also discussed radar reflector localizers such as SAVI SCOUT®, which are small devices that can be placed into a targeted mass at any time prior to lumpectomy. The authors explained that once a surgeon gains a general idea of the mass' location by looking at the post localizer placement mammogram, this localizer is ''hunted'' for intraoperatively using a special handheld device which provides auditory feedback, but does not provide location details until it is found via the auditory feedback. The authors cited a retrospective study at the Moffitt Cancer Center which, according to the authors, indicated that localization using SAVI SCOUT® was successful for 125 out of 129 patients (97 percent, 95 percent Confidence Interval 92–99 percent) and showed that in comparison to wire localization, SAVI SCOUT® provides improved patient comfort and eliminates the need to perform the surgery on the same day as the localization procedure.[41]

Finally, the authors discussed localization using the SmartClip™. The authors noted that the SmartClip™ is the first device to provide three-plane localization information. The authors stated that a monitor displays the approximate position of the SmartClip™ allowing everyone in the operating room to assist with the localization of the SmartClip™ and provide knowledge of its location prior to and throughout the surgery. They further noted that the SmartClip™ localizer can be visualized on a small screen mounted on the electrocautery tool which, similar to the monitor, depicts the direction and depth to the SmartClip™. According to the authors, this provides real-time visual feedback to surgeons as the electrocautery tool moves and allows them to find the clip without having to look up at the operating room monitor. The authors asserted that the three-axis visualization eliminated the need to search for the clip since the location is always known, and that the availability of the SmartClip™ in three colors with different signals eases differentiation between localizers and allows for bracketing of masses.

The authors concluded that wire localization has drawbacks such as wire breakage, patient discomfort, high chances of migration, and narrow placement timeframes, which have been mitigated over the past decade by various soft tissue localizers such as SAVI SCOUT® (radar reflector localizer). The authors concluded that the SmartClip™, which they refer to as a new localizer, may potentially resolve other difficulties encountered with the soft tissue localizers that they currently use. Finally, the authors noted that a clinical study is currently underway at the Moffitt Cancer Center to evaluate the advantages of using the SmartClip™ in clinical practice.

In addition, the applicant provided two physician case reports, each describing the use of the EnVisio™ Navigation System and SmartClip™ in a single patient (62 and 59-year-old female breast cancer patients). Each case report described the patient's history, diagnostic tools utilized, pre-operative, peri-operative, and/or post-operative course, pathology results, as well as the physician's perceptions of the SmartClip™ or EnVisio™ Navigation System. In the first surgical case report,[42] the surgeon noted that the foot pedal activation of the EnVisio™ Navigation System allowed toggling between two SmartClip™ devices, allowing complete dissection around the periphery of the mass to obtain a precise margin. The surgeon asserted that with one marker, there would have been a higher risk of a positive margin. In the second surgical case report,[43] the surgeon similarly noted that the EnVisio™ Navigation System helped her to map out and be more precise in her incision location and lumpectomy dissection.

The applicant also submitted several articles in general support of its application, which we summarize as follows. An article from the Mayo Clinic concluded that intraoperative pathologic assessment with frozen-section margin evaluation of all neoplastic breast specimens allows for immediate re-excision of positive or close margins during the initial operation and results in an extremely low reoperation rate of <2%.[44] Another article addressed the relationship between post-surgery infection and breast cancer recurrence and concluded that there is association between surgical site infection and adverse cancer outcomes, but the cellular link between them remains elusive.[45] Furthermore, a study from the Mayo Clinic concluded there was no reduction in the surgical site infection rate among patients who received postoperative antibiotic prophylaxis after breast surgery.[46] In addition, a study from Washington University School of Medicine concluded that surgical site infection (SSI) after breast cancer surgical procedures was more common than expected for clean surgery and more common than SSI after non-cancer-related breast surgical procedures.[47] A review article from the Department of Radiation Oncology, Case Western Reserve University and University Hospitals in Cleveland surmised that precision medicine holds the promise of truly personalized treatment which provides every individual breast cancer patient with the most appropriate diagnostics and targeted therapies based on the specific cancer's genetic profile as determined by a panel of gene assays and other

[41] Falcon S, Weinfurtner RJ, Mooney B, Niell BL. SAVI SCOUT® localization of breast lesions as a practical alternative to wires: Outcomes and suggestions for trouble-shooting. Clin Imaging. 2018 Nov–Dec;52:280–286. doi: 10.1016/j.clinimag.2018.07.008. Epub 2018 Jul 24. PMID: 30193186.

[42] Kruper, Laura, Bracketing Lobulated Breast Lesion with the EnVisio™ Navigation System using Differentiated SmartClip.

[43] Henkel, Dana, Single SmartClip Case.

[44] Racz JM, Glasgow AE, Keeney GL, Degnim AC, Hieken TJ, Jakub JW, Cheville JC, Habermann EB, Boughey JC. Intraoperative Pathologic Margin Analysis and Re-Excision to Minimize Reoperation for Patients Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2020 Dec;27(13):5303–5311. doi: 10.1 245/s10434–020–08785–z. Epub 2020 Jul 4. PMID: 32623609.

[45] O'Connor RÍ, Kiely PA, Dunne CP. The relationship between post-surgery infection and breast cancer recurrence. J Hosp Infect. 2020 Nov;106(3):522–535. doi: 10.1016/j.jhin.2020.08.004. Epub 2020 Aug 13. PMID: 32800825.

[46] Throckmorton AD, Boughey JC, Boostrom SY, Holifield AC, Stobbs MM, Hoskin T, Baddour LM, Degnim AC. Postoperative prophylactic antibiotics and surgical site infection rates in breast surgery patients. Ann Surg Oncol. 2009 Sep;16(9):2464–9. doi: 10.1245/s10434–009–0542–1. Epub 2009 Jun 9. PMID: 19506959.

[47] Olsen MA, Chu-Ongsakul S, Brandt KE, Dietz JR, Mayfield J, Fraser VJ. Hospital-associated costs due to surgical site infection after breast surgery. Arch Surg. 2008 Jan;143(1):53–60; discussion 61. doi: 10.1001/archsurg.2007.11. PMID: 18209153.

predictive and prognostic tests.[48] An abstract on the subject of prognostic factors for surgical margin status and recurrence in partial nephrectomy concluded that (1) surgical margin positivity after partial nephrectomy is not significantly associated with tumor characteristics and anatomical scoring systems, (2) surgical indication for partial nephrectomy has a direct influence on positive surgical margin rates, and (3) tumor size and stage after partial nephrectomy are valuable parameters in evaluating the recurrence risk.[49] Lastly, a study examining the significance of resection margin in hepatectomy for hepatocellular carcinoma concluded that the width of the resection margin did not influence the postoperative recurrence rates after hepatectomy for hepatocellular carcinoma.[50]

Based on the evidence submitted with the application, we note the following concerns. The first study appears to be unpublished, and it is not clear whether it has been submitted for publication in a peer-reviewed journal. In addition, the study involved a sample of 97 patients from one institution and appears to be written as a feasibility study for a potentially larger randomized control trial. Notably, the authors of this study stated that further studies are required to compare ESL to other non-wire localization techniques to refine which localization technology is most advantageous in breast conservation surgery. Furthermore, the authors did not report the sex or age of the study participants. Additionally, the authors reported that the differences in positive margin and re-excision rates between ESL and WL groups were not statistically significant. We also note a potential concern regarding practice/selection effects bias inherent in the methodology presented.

The second article is an undated,[51] unpublished descriptive clinical paper comparing three different breast mass localization techniques in three cases from one institution. The applicant stated that this paper is pending publication, but provided no further details regarding the status of the paper. The paper did not systematically compare the techniques across any measurable variables, noting that a clinical study was underway at the institution to evaluate the SmartClip™ in clinical practice. Similarly, we note that the physician case reports were solely descriptive in nature—they presented each physician's anecdotal experience using the EnVisio™ Navigation System and SmartClip™. Furthermore, the applicant provided several additional articles that, while informative, did not involve the Navigators and do not appear to directly support the applicant's claim of substantial clinical improvement. We would welcome additional information and evidence from larger, multi-center studies that provide comparative outcomes between the Navigators and existing technologies.

We further note that none of the articles and case reports provided conclusive evidence that the use of the Navigators reduces surgical site infection rates or the risk of tissue marker migration, as claimed by the applicant. In addition, the articles and case reports provided by the applicant described the use of the subject devices only in breast cancer surgery cases. As reported by the applicant, the Navigators can also be used for patients that have biopsy proven cancers in other organs that lack anatomic landmarks like the abdomen and head and neck. We would welcome additional evidence of substantial clinical improvement in cases related to non-breast cancer related procedures.

We are inviting public comments on whether the Navigators meet 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 the Navigators are used in surgical interventions described by the HCPCS codes listed in Table 34.

[48] Eleanor E. R. Harris, ''Precision Medicine for Breast Cancer: The Paths to Truly Individualized Diagnosis and Treatment'', International Journal of Breast Cancer, vol. 2018, Article ID 4809183, 8 pages, 2018. *https://doi.org/10.1155/2018/4809183*.

[49] Demirel HC, Çakmak S, Yavuzsan AH, Yeşildal C, Türk S, Dalkılınç A, Kireççi SL, Tokuç E, Horasanlı K. Prognostic factors for surgical margin status and recurrence in partial nephrectomy. Int J Clin Pract. 2020 Oct;74(10):e13587. doi: 10.1111/ijcp.13587. Epub 2020 Jul 14. PMID: 32558097.

[50] Poon, R.T., Fan, S.T., Ng, I O., & Wong, J. (2000). Significance of resection margin in hepatectomy for hepatocellular carcinoma: A critical reappraisal. *Annals of surgery, 231*(4), 544–551. *https://doi.org/10.1097/00000658-200004000-00014*.

[51] Although the applicant reported the date of the study as January 2021, the copy of the study provided by the applicant was not dated.

TABLE 34: HCPCS CODES REPORTED WITH THE NAVIGATORS

HCPCS Code	Long Descriptor	SI	APC
19101	Biopsy of breast; open, incisional	J1	5091
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)	J1	5091
19125	Excision of breast lesion identified by preoperative placement of radiological marker, open; single lesion	J1	5091
21552	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; 3 cm or greater	J1	5073
22902	Excision, tumor, soft tissue of abdominal wall, subcutaneous; less than 3 cm	J1	5072
38500	Biopsy or excision of lymph node(s); open, superficial	J1	5091
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	S	5241
38525	Biopsy or excision of lymph node(s); open, deep axillary node(s)	J1	5091
38530	Biopsy or excision of lymph node(s); open, internal mammary node(s)	J1	5091
38740	Axillary lymphadenectomy; superficial	J1	5361

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5072—Level 2 Excision/Biopsy/Incision and Drainage, which had a CY 2021 payment rate of $1,407 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 22902 had a device offset amount of $1.13 at the time the application was received. According to the applicant, the cost of the Navigators is $499.

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 $499 for the Navigators is 35.5 percent of the applicable APC payment amount for the service related to the category of devices of $1,407 (($499/$1,407) × 100 = 35.5 percent). Therefore, we believe the Navigators meet the first cost significance requirement.

The second cost significance requirement, 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 $499 for the Navigators is 44,159.3 percent of the cost of the device-related portion of the APC payment amount for the related service of $1.13 (($499/$1.13) × 100 = 44,159.3 percent). Therefore, we believe that the Navigators meet the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $499 for the Navigators and the portion of the APC payment amount for the device of $1.13 is 35.4 percent of the APC payment amount for the related service of $1,407 ((($499 − $1.13)/$1,407) × 100 = 35.4 percent). Therefore, we believe that the Navigators meet the third cost significance requirement.

We are inviting public comment on whether the Navigators meet the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(3) SmartClip™

Elucent Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for CY 2023 for the SmartClip™ Soft Tissue Marker (SmartClip™). The applicant described the SmartClip™ as an electromagnetically activated, single-use, sterile soft tissue marker used for anatomical surgical guidance. According to the applicant, the SmartClip™ is the only soft tissue marker that delivers independent coordinates of location when used in conjunction with the applicant's EnVisio™ Navigation System (which includes the Navigators discussed

previously in this proposed rule). Per the applicant, at the time of surgical intervention, electromagnetic waves delivered by the EnVisio™ Navigation System activate the implanted SmartClip™ within a 50cm × 50cm × 35cm volume. The applicant further explained that the SmartClip™ contains an application-specific integrated circuit (ASIC), customized for use with the EnVisio™ Navigation System, which is activated at a specific frequency and communicates to the EnVisio™ Navigation System the precise, real-time location of both the SmartClip™ and the surgical margin, enabling the surgeon to plan the specimen (tumor and margin) for excision.[52] The applicant asserted that this data is calibrated relative to the tip of the electrocautery device or other operating instrument and is displayed in 3D.

The applicant stated that the SmartClip™ is assembled into a hermetically sealed, Parylene C coated glass cylinder and provided pre-loaded into a 15-gauge introducer needle available in various lengths (5cm, 7.5cm, 10cm). Per the applicant, using the introducer needle, the SmartClip™ is implanted directly into a tumor at the time of biopsy or during a separate procedure in advance of surgery. According to the FDA 510(k) Summary (K180640), the SmartClip™ can be implanted into various types of soft tissue, such as lung, gastrointestinal system, and breast, and can subsequently be detected using the EnVisio™ Navigation System or by means of radiography (including mammographic imaging), ultrasound, and magnetic resonance imaging (MRI). Per the applicant, it is utilized frequently in breast conserving surgery, lymph nodes, and head/neck cancers.

According to the applicant, up to three SmartClips™, each with a unique electromagnetic signature, can be implanted in a patient to mark and provide continuous location of multiple targets (for example, 3 lesions, or 2 lesions/1 lymph node) or to bracket either a large lesion or microcalcifications. The applicant claimed that the SmartClip™ enables the surgeon to choose the safest, least disfiguring (oncoplastic) approach and path to the tumor before the surgery. According to the applicant, providing surgical planning and excision lessens the impact of the disruption of non-targeted tissue. In addition, the applicant stated that the SmartClip™ enables the surgeon to measure and record specimen size post excision.

The applicant further asserted that the SmartClip™ is a significantly advanced version of an interstitial implant device, such as a gold fiducial marker, that is placed into a tumor directly to guide the surgeon to the location of a malignant lesion. The applicant claimed that the SmartClip™ has characteristics that differentiate it from conventional fiducial markers. First, the applicant stated that the SmartClip™ location is expressed relative to the patient's position—medial/lateral, inferior/superior, anterior/posterior with 2mm precision. Second, according to the applicant, the SmartClip™ location is instantaneous and updated 16 times per second reflecting any location change due to tissue manipulation and allowing alterations in the patient's position with no compromise in accuracy. Furthermore, the applicant asserted that the SmartClip™ provides seamless, real-time navigation, maintaining the 3D position of the lesion within the surgical space and relative to the surgical tools. The applicant added that the SmartClip™ is not subject to registration errors often seen with navigation that utilizes pre-procedure imaging for guidance. Furthermore, the applicant asserted that the SmartClip™ is ideal for minimally invasive procedures in that it does not require line of sight. The applicant also stated that the SmartClip™ does not utilize any radioactive materials or contain any ionizing radiation. Per the applicant, the SmartClip™ does not require a separate imaging modality, however, if another imaging modality is utilized, the SmartClip™ is radiopaque. Finally, the applicant stated that the SmartClip™ provides the following advantages compared to current localization methods (including preoperative wire localization): (1) no migration of the SmartClip™; (2) no depth limitation, addressing broader patient population clinical needs; (3) no limitations on clinical approach for placement or surgical excision; (4) permanently implantable, should continuum of care change; (5) no risks for multifocal or extensive lesion markings for complex cases; (6) no required workflow changes for varied surgical tools; (7) can be placed remote from surgery (days or weeks) at the patient's convenience; (8) nothing protruding from the skin so there is no mechanical pathway for bacterial contamination; and (9) puncture is healed at the time of surgery.

With respect to the newness criterion at § 419.66(b)(1), on June 4, 2018, the applicant received 510(k) clearance from FDA to market the SmartClip™ for radiographic marking of sites in soft tissue and in situations where the soft tissue site needs to be marked for future medical procedures. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the SmartClip™ on February 28, 2022, which is more than 3 years from the date of the initial FDA marketing authorization. We note that in accordance with 42 CFR 419.66(b)(1), the pass-through payment application for a medical device must be submitted within 3 years from the date of the initial FDA approval or clearance, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case we will consider the pass-through payment application if it is submitted within 3 years from the date of market availability. The applicant asserted that the SmartClip™ could not be marketed until May 2019 because it is utilized in conjunction with the EnVisio™ Navigation System and FDA clearance for the EnVisio™ Navigation System was required prior to use of the SmartClip™ (as mentioned previously, the applicant received FDA clearance for the EnVisio™ Navigation System on March 22, 2019). We note that, according to the FDA 510(k) Summary and Indications for Use for the SmartClip™ (K180640) and the EnVisio™ Navigation System (K183400), the SmartClip™ also can be located and surgically removed through the use of imaging guidance such as x-ray, mammography, ultrasound, and MRI. According to the applicant, the EnVisio™ Navigation System enables the SmartClip™ as an intelligent interstitial soft tissue marker utilizing electromagnetic waves to display precise coordinates in each of three planes. The applicant further asserted that the SmartClip™ was designed to provide the surgeon the precise coordinates for target tissue removal and that this function requires the utilization of the electronic field generated by the EnVisio™ Navigation System. The applicant noted that while the SmartClip™ is visible and can be located using imaging guidance (such as ultrasound, MRI, or radiography), such imaging guidance would typically only be used in the removal of the targeted tissue should the SmartClip™ ASIC fault, so as to ensure patient care is not compromised. The applicant further stated that it did not consider pursuing

[52] Based on the FDA 510(k) Summary for the EnVisio™ Navigation System, the SmartClip™ does not appear to be a component of the EnVisio™ Navigation System; the SmartClip™ has a separate FDA 510(k) clearance as discussed later in this section.

marketability of the SmartClip™ as an unintelligent interstitial marker as the applicant believed that the action would not have resulted in meeting the unmet healthcare need for substantial clinical improvements. In addition, the applicant claimed that due to the impact of the COVID–19 pandemic, ambulatory surgical centers and outpatient facilities were restricted in performing breast cancer surgery, resulting in a verifiable delay. The applicant requested that CMS utilize the FDA clearance date for the EnVisio™ Navigation System (March 22, 2019) as the applicable date for the SmartClip™'s initial marketability. We are inviting public comments on whether the SmartClip™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the SmartClip™ 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. The applicant did not indicate whether the SmartClip™ meets the device eligibility requirements of § 419.66(b)(4), which provide that the device may not be any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker). We are inviting public comments on whether the SmartClip™ meets the eligibility criteria at § 419.66(b).

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. The applicant stated that it was not aware of an existing pass-through payment category that describes the SmartClip™.

The applicant identified three devices or device categories that it believes are most closely related to the SmartClip™: (1) hook-wire systems (the applicant did not provide an associated code, but listed Kopans (Bard and McKesson) and Dualok (McKesson) as types of such systems); (2) HCPCS code A4648 (Tissue marker, implantable, any type, each); and (3) HCPCS code 91112 (Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report (Smartpill™)).[53]

Although HCPCS code A4648 is not an existing pass-through payment category, we note that a previous equivalent code, HCPCS code C1879 (Tissue marker (implantable)), was a pass-through payment category in effect between August 1, 2000 and December 31, 2002.[54] Pursuant to Change Request 8338, CMS deleted temporary HCPCS code C1879 on June 30, 2013, because this category of devices was described by permanent HCPCS code A4648. We stated in the Change Request that effective July 1, 2013, when using implantable tissue markers with any services provided in the OPPS, providers should report the use and cost of the implantable tissue marker with HCPCS code A4648 only.[55] According to the applicant, tissue markers described by HCPCS code A4648 are passive mechanical localization devices. The applicant explained that such tissue markers are generally made of gold or other radiographically opaque substances (usually metal). Per the applicant, compared to the SmartClip™, such tissue markers do not provide margin or 3D information, do not update in real-time, and require advanced radiographic capability (computed tomography, fluoroscopy, ultrasound) in order to be detected and localized. According to the applicant, these markers are only useful because they are visible either radiographically or to the naked eye. The applicant identified two types of gold fiducial markers—generic gold fiducial marker (IZI Medical) and generic soft tissue gold marker (Civco). The applicant explained that the SmartClip™ is an advanced interstitial implant that substantially improves upon both generic gold fiducial markers and common hook-wire localization systems. According to the applicant, passive mechanical tissue markers such as gold fiducial markers and hook-wire systems are related devices created for roughly the same purpose as the SmartClip™, but neither can be considered an adequate comparator due to the highly advanced technology embedded in the SmartClip™. In contrast to both generic gold fiducial markers and hook-wire systems, the applicant asserted that the SmartClip™ contains an ASIC which is activated at a specific frequency and provides location information regarding both the SmartClip™ and the surgical margins to the operating physician in near real-time. The applicant claimed that it is not aware of any other device that has this functionality. The applicant added that this data is calibrated relative to the tip of an electrocautery device or other operating instrument and is displayed in 3D so that the surgeon has an objective method of obtaining a negative concentric margin. According to the applicant, this is particularly useful for posterior and deep margins for which passive localization devices provide no information. The applicant asserted that it does not believe that the SmartClip™ is described by HCPCS code A4648.

We are inviting public comments on whether the SmartClip™ meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

The applicant claimed that the use of the SmartClip™ results in substantial clinical improvement over existing technologies by, (1) reducing positive margin and re-excision rates, thereby decreasing the rate of subsequent therapeutic interventions; (2) reducing the rate of device-related complications, including surgical site infections and wire migration and transection; and (3) improving the surgical approach (surgeons are not tethered to the best radiological approach, and the incision can be placed in the ideal location resulting in better oncoplastic results,

[53] HCPCS code 91112 is not a current or previous pass-through payment category. According to the applicant, the Smartpill™ is an ingestible pill that is tracked using a wearable device for short term pH and pressure testing for intestinal tract diagnostics. By contrast, the applicant noted that the SmartClip™ is permanently implantable within soft tissue to direct a surgeon for the purposes of removal of a lesion and margin.

[54] Medicare Claims Processing Manual, Ch. 4, section 60.4.2.

[55] Change Request 8338, June 7, 2013. The Medicare Claims Processing Manual further defines the devices encompassed by HCPCS code C1879 as material that is placed in subcutaneous or parenchymal tissue (may also include bone) for radiopaque identification of an anatomic site and adds that these markers are distinct from topical skin markers, which are positioned on the surface of the skin to serve as anatomical landmarks. Medicare Claims Processing Manual, Ch. 4, section 60.4.3.

less complex path to the lesion, and better visualization during surgery). The applicant provided articles and case reports for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that use of the SmartClip™ reduces positive margin and re-excision rates, the applicant submitted an abstract of a study performed to assess the impact of electromagnetic seed localization (ESL) using the EnVisio™ Navigation System and SmartClip™ compared to wire localization (WL) on operative times, specimen volumes, margin positivity, and margin re-excision rates.[56] Between August 2020 and August 2021, 97 patients underwent excisional biopsy (n=20), or lumpectomy with (n=53) or without (n=24) sentinel lymph node biopsy (SLNB) using ESL guidance at a single institution by 5 surgeons. The study authors matched these patients, one-to-one, with WL patients undergoing surgery between 2006 and 2021 based on surgeon, procedure type with stratification for those having and not having nodal procedures, and pathologic stage or benign pathology. When greater than one WL match was found, selection was randomized. The authors compared continuous variables (operative times, specimen volumes, excess volume excised) between patients undergoing ESL and WL using Wilcoxon rank sums tests. The authors compared categorical variables (positive margin rates, re-excision rates) using Fisher's exact tests. Median operative time for ESL versus WL for lumpectomy with SLNB was 66 versus 69 minutes (p=0.76) and without SLNB was 40 versus 34.5 minutes (p=0.17). Median specimen volume was 55cm^3 with WL versus 36cm^3 with ESL (p=0.0012). In those with measurable tumor volume, excess tissue excised was larger with WL compared to ESL (median=73.2cm^3 versus 52.5cm^3, p=0.017). Main segment margins were positive in 18 of 97 (19 percent) WL patients compared to 10 of 97 (10 percent) ESL patients (p=0.17). In the WL group, 13 of 97 (13 percent) had margin re-excision at a separate procedure, compared to 6 of 97 (6 percent) in the ESL group, (p=0.15). The authors concluded that ESL is superior to WL because it provided more accurate localization, evidenced by smaller specimen volume with less excess tissue excised, despite similar operative times. In addition, the authors reported that, although not statistically significant, ESL resulted in lower positive margin rates and lower margin re-excision rates compared to WL. The authors further noted that ESL allows for preoperative localization, eliminating same day operative delays, and single tool, 3D localization. The authors concluded that further studies comparing ESL to other non-wire localization techniques are required to refine which localization technology is most advantageous in breast conservation surgery.

The applicant provided a second article consisting of a clinical paper from the Moffitt Cancer Center that, per the applicant, is pending publication.[57] The paper presented three cases from the Moffitt Cancer Center, including radiographic and other images, employing three different methods of breast mass localization: (1) SmartClip™, (2) SAVI SCOUT® radar reflector localizer, and (3) traditional wire localizer. The authors stated that the purpose of the paper was to educate the audience about the technological advances regarding breast mass localization and to discuss the advantages and disadvantages of SmartClip™ localizers, SAVI SCOUT® localizers, and wire localizers.

The authors first discussed wire localization, stating that wire localization involves image-guided insertion of a guidewire into a targeted mass and that the use of multiple wires allows for bracketing of multiple lesions or a large lesion. The authors asserted that, while effective in localization, this procedure has drawbacks such as wire breakage, patient discomfort, wire migration while moving or transporting the patient, and the need to surgically remove the wire the same day that it is placed due to this risk of migration.

The authors also discussed radar reflector localizers such as SAVI SCOUT®, which are small devices that can be placed into a targeted mass at any time prior to lumpectomy. The authors explained that once a surgeon gains a general idea of the mass' location by looking at the post localizer placement mammogram, this localizer is ''hunted'' for intraoperatively using a special handheld device which provides auditory feedback, but does not provide location details until it is found via the auditory feedback. The authors cited a retrospective study at the Moffitt Cancer Center which, according to the authors, indicated that localization using SAVI SCOUT ® was successful for 125 out of 129 patients (97 percent, 95 percent Confidence Interval 92–99 percent) and showed that in comparison to wire localization, SAVI SCOUT® provides improved patient comfort and eliminates the need to perform the surgery on the same day as the localization procedure.[58]

Finally, the authors discussed localization using the SmartClip™. The authors noted that the SmartClip™ is the first device to provide three-plane localization information. The authors stated that a monitor displays the approximate position of the SmartClip™ allowing everyone in the operating room to assist with the localization of the SmartClip™ and provide knowledge of its location prior to and throughout the surgery. They further noted that the SmartClip™ localizer can be visualized on a small screen mounted on the electrocautery tool which, similar to the monitor, depicts the direction and depth to the SmartClip™. According to the authors, this provides real-time visual feedback to surgeons as the electrocautery tool moves and allows them to find the clip without having to look up at the operating room monitor. The authors asserted that the three-axis visualization eliminated the need to search for the clip since the location is always known, and that the availability of the SmartClip™ in three colors with different signals eases differentiation between localizers and allows for bracketing of masses.

The authors concluded that wire localization has drawbacks such as wire breakage, patient discomfort, high chances of migration, and narrow placement timeframes, which have been mitigated over the past decade by various soft tissue localizers such as SAVI SCOUT® (radar reflector localizer). The authors concluded that the SmartClip™, which they refer to as a new localizer, may potentially resolve other difficulties encountered with the soft tissue localizers that they currently use. Finally, the authors noted that a clinical study is currently underway at the Moffitt Cancer Center to evaluate the advantages of using the SmartClip™ in clinical practice.

[56] Jordan R, Rivera-Sanchez L, Kelley K, O'Brien M, et al. The Impact of an Electromagnetic Seed Localization Device as Versus Wire Localization on Breast Conserving Surgery: A Matched Pair Analysis. Abstract presented at: 23rd Annual Meeting of The American Society of Breast Surgeons; April 6–10, 2022. *https://www.breastsurgeons.org/meeting/2022/docs/2022_Official_Proceedings_ASBrS.pdf.*.

[57] Ibanez J, Wotherspoon T, Mooney B, Advances in Image Guided Breast Mass Localization Techniques (undated). Submitted by the applicant with its application on February 28, 2022.

[58] Falcon S, Weinfurtner RJ, Mooney B, Niell BL. SAVI SCOUT® localization of breast lesions as a practical alternative to wires: Outcomes and suggestions for trouble-shooting. Clin Imaging. 2018 Nov-Dec;52:280–286. doi: 10.1016/j.clinimag.2018.07.008. Epub 2018 Jul 24. PMID: 30193186.

In addition, the applicant provided three physician case reports (two by surgeons and one by radiologists), each describing the use of the SmartClip™ in a single patient (62, 59, and 53-year-old female breast cancer patients). Each case report described the patient's history, diagnostic tools utilized, pre-operative, peri-operative, and/or post-operative course, pathology results, as well as the physician's perceptions of the SmartClip™ or EnVisio™ Navigation System. In the first surgical case report,[59] the surgeon noted that the foot pedal activation of the EnVisio™ Navigation System allowed toggling between two SmartClip™ devices, allowing complete dissection around the periphery of the mass to obtain a precise margin. The surgeon asserted that with one marker, there would have been a higher risk of a positive margin. In the second surgical case report,[60] the surgeon similarly noted that the EnVisio™ Navigation System helped her to map out and be more precise in her incision location and lumpectomy dissection. Finally, in the radiologists' case report,[61] ultrasound guided SmartClip™ localization was ordered for definitive surgical management. The radiologists noted the visibility of the SmartClip™ relative to the coil clip, mass, and surrounding tissue, as well as the ease of the deployment.

The applicant also submitted several articles in general support of its application, which we summarize as follows. An article from the Mayo Clinic concluded that intraoperative pathologic assessment with frozen-section margin evaluation of all neoplastic breast specimens allows for immediate re-excision of positive or close margins during the initial operation and results in an extremely low reoperation rate of <2 percent.[62] Another article addressed the relationship between post-surgery infection and breast cancer recurrence and concluded that there is association between surgical site infection and adverse cancer outcomes, but the cellular link between them remains elusive.[63] Furthermore, a study from the Mayo Clinic concluded there was no reduction in the surgical site infection rate among patients who received postoperative antibiotic prophylaxis after breast surgery.[64] In addition, a study from Washington University School of Medicine concluded that surgical site infection (SSI) after breast cancer surgical procedures was more common than expected for clean surgery and more common than SSI after non-cancer-related breast surgical procedures.[65] A review article from the Department of Radiation Oncology, Case Western Reserve University and University Hospitals in Cleveland surmised that precision medicine holds the promise of truly personalized treatment which provides every individual breast cancer patient with the most appropriate diagnostics and targeted therapies based on the specific cancer's genetic profile as determined by a panel of gene assays and other predictive and prognostic tests.[66] An abstract on the subject of prognostic factors for surgical margin status and recurrence in partial nephrectomy concluded that (i) surgical margin positivity after partial nephrectomy is not significantly associated with tumor characteristics and anatomical scoring systems, (ii) surgical indication for partial nephrectomy has a direct influence on positive surgical margin rates, and (iii) tumor size and stage after partial nephrectomy are valuable parameters in evaluating the recurrence risk.[67] Lastly, a study examining the significance of resection margin in hepatectomy for hepatocellular carcinoma concluded that the width of the resection margin did not influence the postoperative recurrence rates after hepatectomy for hepatocellular carcinoma.[68]

Based on the evidence submitted with the application, we note the following concerns. The first study appears to be unpublished, and it is not clear whether it has been submitted for publication in a peer-reviewed journal. In addition, the study involved a sample of 97 patients from one institution and appears to be written as a feasibility study for a potentially larger randomized control trial. Notably, the authors of this study stated that further studies are required to compare ESL to other non-wire localization techniques to refine which localization technology is most advantageous in breast conservation surgery. Furthermore, the authors did not report the sex or age of the study participants. Additionally, the authors reported that the differences in positive margin and re-excision rates between ESL and WL groups were not statistically significant. We also note a potential concern regarding practice/selection effects bias inherent in the methodology presented.

The second article is an undated,[69] unpublished descriptive clinical paper comparing three different breast mass localization techniques in three cases from one institution. The applicant stated that this paper is pending publication, but provided no further details regarding the status of the paper. The paper did not systematically compare the techniques across any measurable variables, noting that a clinical study was underway at the institution to evaluate the SmartClip™ in clinical practice. Similarly, we note that the physician case reports were solely descriptive in nature—they presented each physician's anecdotal experience using the EnVisio™ Navigation System and/or SmartClip™. Furthermore, the applicant provided several additional articles that, while informative, did not involve the SmartClip™ and do not appear to directly support the applicant's claim of substantial clinical improvement. We would welcome additional information and evidence from larger, multi-center studies that provide comparative outcomes between the SmartClip™ and existing technologies.

[59] Kruper, Laura, Bracketing Lobulated Breast Lesion with the EnVisio™ Navigation System using Differentiated SmartClip.

[60] Henkel, Dana, Single SmartClip Case.

[61] Lee, Marie C., Mooney, Blaise, Right Breast IDC/DCIS.

[62] Racz JM, Glasgow AE, Keeney GL, Degnim AC, Hieken TJ, Jakub JW, Cheville JC, Habermann EB, Boughey JC. Intraoperative Pathologic Margin Analysis and Re-Excision to Minimize Reoperation for Patients Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2020 Dec;27(13):5303–5311. doi: 10.1245/s10434–020–08785–z. Epub 2020 Jul 4. PMID: 32623609.

[63] O'Connor RÍ, Kiely PA, Dunne CP. The relationship between post-surgery infection and breast cancer recurrence. J Hosp Infect. 2020 Nov;106(3):522–535. doi: 10.1016/j.jhin.2020.08.004. Epub 2020 Aug 13. PMID: 32800825.

[64] Throckmorton AD, Boughey JC, Boostrom SY, Holifield AC, Stobbs MM, Hoskin T, Baddour LM, Degnim AC. Postoperative prophylactic antibiotics and surgical site infection rates in breast surgery patients. Ann Surg Oncol. 2009 Sep;16(9):2464–9. doi: 10.1245/s10434–009–0542–1. Epub 2009 Jun 9. PMID: 19506959.

[65] Olsen MA, Chu-Ongsakul S, Brandt KE, Dietz JR, Mayfield J, Fraser VJ. Hospital-associated costs due to surgical site infection after breast surgery. Arch Surg. 2008 Jan;143(1):53–60; discussion 61. doi: 10.1001/archsurg.2007.11. PMID: 18209153.

[66] Eleanor E.R. Harris, ''Precision Medicine for Breast Cancer: The Paths to Truly Individualized Diagnosis and Treatment'', International Journal of Breast Cancer, vol. 2018, Article ID 4809183, 8 pages, 2018. *https://doi.org/10.1155/2018/4809183*.

[67] Demirel HC, Çakmak S, Yavuzsan AH, Yeşildal C, Türk S, Dalkılınç A, Kireççi SL, Tokuç E, Horasanlı K. Prognostic factors for surgical margin status and recurrence in partial nephrectomy. Int J Clin Pract. 2020 Oct;74(10):e13587. doi: 10.1111/ijcp.13587. Epub 2020 Jul 14. PMID: 32558097.

[68] Poon, R.T., Fan, S.T., Ng, I.O., & Wong, J. (2000). Significance of resection margin in hepatectomy for hepatocellular carcinoma: A critical reappraisal. *Annals of surgery, 231*(4), 544–551. *https://doi.org/10.1097/00000658-200004000-00014*.

[69] Although the applicant reported the date of the study as January 2021, the copy of the study provided by the applicant was not dated.

We further note that none of the articles and case reports provide conclusive evidence that the use of the SmartClip™ reduces surgical site infection rates or the risk of tissue marker migration, as claimed by the applicant. In addition, the articles and case reports provided by the applicant described the use of the subject devices only in breast cancer surgery cases. As reported by the applicant, the SmartClip™ is utilized frequently in breast conserving surgery, lymph nodes, and head/neck cancers. We would welcome additional evidence of substantial clinical improvement in cases related to non-breast cancer related procedures. We are inviting public comments on whether the SmartClip™ 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. We note that the applicant stated that up to three SmartClips™ can be implanted in a patient to mark and provide continuous location of multiple targets, however, the applicant did not provide data on the average number of SmartClips™ used per patient. The applicant stated that the SmartClip™ is used in procedures described by the HCPCS codes in Table 35.

TABLE 35: HCPCS CODES REPORTED WITH THE SMARTCLIP™

HCPCS Code	Long Descriptor	SI	APC
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance	J1	5072
19281	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance	Q1	5071
19283	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance	Q1	5071
19825	**	**	**
49180	Biopsy, abdominal or retroperitoneal mass, percutaneous needle	J1	5072
38505	Biopsy or excision of lymph node(s); by needle, superficial (eg, cervical, inguinal, axillary)	J1	5072
A4648	N/A	N/A	N/A
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	T	5301

** HCPCS code 19825 does not exist and thus we could not evaluate it as part of the cost criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations related to the SmartClip™, we used APC 5071—Level 1 Excision/Biopsy/Incision and Drainage, which had a CY 2021 payment rate of $621.97 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 19281 had a device offset amount of $219.87 at the time the application was received. According to the applicant, the cost of the SmartClip™ is $375.

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 $375 for the SmartClip™ is 60.3 percent of the applicable APC payment amount for the service related to the category of devices of $621.97 (($375/$621.97) × 100 = 60.3 percent). Therefore, we believe the SmartClip™ meets the first cost significance requirement.

The second cost significance requirement, 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 $375 for the SmartClip™ is 170.6 percent of the cost of the device-related portion of the APC payment amount for the related service of $219.87 (($375/$219.87) × 100 = 170.6 percent). Therefore, we believe that the SmartClip™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $375 for the SmartClip™ and the portion of the APC payment amount for the device of $219.87 is 24.9 percent of the APC payment amount for the related service of $621.97 ((($375 − $219.87)/$621.97) × 100 = 24.9 percent). Therefore, we believe that the SmartClip™ meets the third cost significance requirement.

We are inviting public comment on whether the SmartClip™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(4) Evoke® Spinal Cord Stimulation (SCS) System

Saluda Medical Inc. submitted an application for a new device category for transitional pass-through payment status for the Evoke® Spinal Cord Stimulation (SCS) System for CY 2023. The applicant described the Evoke® SCS System as a rechargeable, upgradeable, implantable spinal cord stimulation system that provides closed-loop stimulation controlled by measured evoked compound action potentials (ECAPs). According to the applicant, the Evoke® SCS System is used in the treatment of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. Per the applicant, the Evoke® SCS System's rechargeable battery is indicated for use up to 10 years.

The applicant explained that SCS consists of applying an electrical stimulus to the spinal cord which causes the activated fibers (*e.g.,* Aβ-fibers) to generate action potentials. Aβ-fibers are the low-threshold sensory fibers in the dorsal column that contribute to inhibition of pain signals in the dorsal horn. The action potentials summed together form the ECAP. Therefore, the applicant asserted that ECAPs are a direct measure of spinal cord fiber activation that generates pain inhibition for an individual.

According to the applicant, the Evoke® SCS System is comprised of 5 implanted and 12 external components. The applicant identified the following five implanted components of the Evoke® SCS System: (1) Closed Loop Stimulator (CLS): a rechargeable, 25-channel implantable pulse generator (IPG or stimulator) which generates an electrical stimulus and measures and records the nerve fibers' response to stimulus (*i.e.,* ECAPs). Although named ''Closed Loop Stimulator,'' the applicant indicated that this stimulator delivers both open-loop and closed-loop stimulation modes; (2) Percutaneous Leads: Electrical current is delivered to the spinal cord via the electrodes on leads that are introduced into the epidural space through an epidural needle and connected to the stimulator. Per the applicant, ECAPs are measured using two non-stimulating contacts of the leads; (3) Lead Extension: Used to provide additional length if needed to connect the implanted lead to the CLS or external closed-loop stimulator (eCLS); (4) Suture Anchors and Active Anchors: Used to anchor the lead to the supraspinous ligament or deep fascia; and (5) CLS Port Plug: Used to block unused ports in the CLS header. Additionally, the applicant stated there are 12 external components of the Evoke® SCS System (*e.g.,* surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers).

According to the applicant, the Evoke® SCS System is the first and only SCS system that provides closed-loop stimulation. In closed-loop stimulation, the system automatically measures the impact of the prior stimulation signal on the nerve and adjusts the next stimulation signal accordingly to maintain the prescribed physiologic response. Per the applicant, this closed feedback loop provides consistency in the stimulation received by the nerve as opposed to the stimulation emitted from the device.

The applicant stated that the Evoke® SCS System measures ECAPs and adjusts the next stimulation accordingly as follows: (1) the Evoke® SCS System measures ECAPs following every stimulation pulse from two electrodes not involved in stimulation; (2) the recorded ECAP signal is sampled by the stimulator and provides a measurement of the ECAP amplitude; and (3) the Evoke® SCS System utilizes the ECAPs in a feedback mechanism to adjust the next stimulation pulse, thereby delivering closed-loop stimulation. The feedback mechanism minimizes the difference between the measured ECAP amplitude and the ECAP amplitude target by automatically adjusting the stimulation current for every stimulus. In doing so, the applicant asserted it maintains spinal cord activation near the target level. According to the applicant, this addresses the challenge all currently available SCS systems face regarding the ever-changing distance between the electrode and spinal cord that results in variable spinal cord activation, and thus, less effective therapy. Per the applicant, although there have been numerous technological advances in SCS therapy over the years, every other SCS system on the market provides open-loop stimulation, where parameters are set by the physician and the patient can only modulate those parameters within defined limits based upon how they feel. However, physiological functions such as breathing, heartbeat and posture changes alter the distance between the spinal cord target fibers and SCS electrodes. Therefore, the applicant asserted that the number of nerve fibers activated by open-loop stimulation continually changes, resulting in inconsistent therapy delivery (*i.e.,* under- or over-stimulation) and that ECAP-controlled closed-loop therapy produces a significantly higher degree of spinal cord activation that is maintained within the therapeutic window which drives superior outcomes. The applicant asserted that a consistent neural response at the prescribed level may only be achieved with a closed-loop system that continually adjusts on every stimulation pulse.

With respect to the newness criterion at § 419.66(b)(1), on February 28, 2022, the Evoke® SCS System received PMA approval from FDA as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Evoke® SCS System on March 1, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the Evoke® SCS System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the Evoke® SCS System is integral to the service of treating and managing chronic intractable pain of the trunk and/or limbs using spinal cord stimulation. The applicant noted that some components of the system (described previously) are implanted in a patient and are in contact with human tissue. The applicant indicated that all components of the system are used for one patient only. We note that the external components of the Evoke® SCS System (referenced previously) are not implanted in a patient and do not come in contact with human tissue as required by § 419.66(b)(3). The applicant did not indicate whether the Evoke® SCS System meets the device eligibility requirements of § 419.66(b)(4) in regard to whether it is an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, or whether it is a supply or material furnished incident to a service. We note that some of the external components (*e.g.,* surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) noted previously may be considered capital as specified under § 419.66(b)(4). We are inviting public comments on whether the Evoke® SCS System meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion for establishing a device category, 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. The applicant asserted that none of the existing categories appropriately describe the Evoke® SCS System. The applicant provided a list of current and prior device categories for pass-through payments for other spinal cord stimulation systems (described in Table 36) and explained why each category does not describe the Evoke® SCS System. In summary, the applicant asserted that the existing codes do not adequately describe the Evoke® SCS System because the existing codes apply to devices that: provide stimulation to organs other than the spinal cord (*e.g.,* heart, transvenous sensing and stimulation, baroreceptors in the carotid artery), only provide open-loop stimulation, and are non-rechargeable. According to the applicant, the Evoke® SCS System is a rechargeable, closed-loop neurostimulator that provides stimulation to spinal nerves. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to the Evoke® SCS System. We are inviting public comment on whether Evoke® SCS System meets the device category criterion.

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TABLE 36: POTENTIAL EXISTING/PREVIOUS DEVICE CATEGORIES

HCPCS Code	Device Category	Why Category Does Not Include Evoke® SCS System
C1824	Generator, cardiac contractility modulation (implantable)	This category describes a generator that provides cardiac contractility modulation to the right ventricle in the heart. The Evoke SCS System does not provide stimulation to the heart. Therefore, this category does not describe the Evoke SCS System.
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	This category describes neurostimulators that are rechargeable, and provide high frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not describe neurostimulators that provide closed-loop stimulation. As the Evoke SCS System is a closed-loop neurostimulator, this category does not appropriately describe this technology.
C1767	Generator, neurostimulator (implantable), non-rechargeable	This category describes neurostimulators that are non-rechargeable and provide non-high-frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not describe neurostimulators that provide closed-loop stimulation. As the Evoke SCS System is a rechargeable, closed-loop neurostimulator, this category does not appropriately describe this technology.
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	This category describes neurostimulators that are rechargeable, and provide non-high-frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not

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The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant asserted that the Evoke® SCS System represents a substantial clinical improvement over existing technology because its use of closed-loop stimulation provides greater improvements in key clinical outcomes over the open-loop stimulation that is currently used in existing technologies. Specifically, the applicant stated that the closed-loop stimulation of the Evoke® SCS System provides: (1) a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications in comparison to Open-Loop SCS at 3 and 12 months; (2) greater percentage change in back pain measured by Visual Analog Scale at 3 and 12 months; (3) greater incidence of 50 percent reduction in back pain at 3 and 12 months; (4) greater incidence of 50 percent reduction in leg pain at 12 months; (5) greater incidence of 80 percent reduction in overall back and leg pain at 12 months; (6) consistently greater visual improvement in remaining secondary endpoint measures at 3 and 12 months; (7) a balanced safety profile between treatment groups; (8) a greater percentage of time in the therapeutic window for closed-loop patients compared to open-loop patients; (9) maintenance of clinical improvements in pain response and pain reduction at 24 months post-

implantation; and (10) the results for the pivotal trial treatment group have been replicated in another multi-center trial with 12-month follow-up. With respect to this criterion, the applicant submitted three articles that supported these ten claims regarding the impact of the Evoke® SCS System on the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

The first article provided by the applicant in support of claims 1–8 was for the Evoke pivotal clinical study, a prospective, multicenter, double-blind, randomized controlled trial designed to compare the use of ECAP-controlled, closed-loop stimulation to open-loop stimulation for the treatment of back and leg pain.[70] The trial was done at 13 specialist clinics, academic centers, and hospitals in the USA. Patients with chronic, intractable pain of the back and legs (Visual Analog Scale [VAS] pain score ≥60 mm; Oswestry Disability Index [ODI] score 41–80) who were refractory to conservative therapy, on stable pain medications, had no previous experience with spinal cord stimulation, and were appropriate candidates for a spinal cord stimulation trial were screened. Eligible patients were randomly assigned (1:1) to receive ECAP-controlled closed-loop spinal cord stimulation (investigational group) or fixed-output, open-loop spinal cord stimulation (control group). A total of 134 subjects (67 subjects in each treatment group) were randomized. Patients, investigators, and site staff were masked to the treatment assignment. The primary outcome was the proportion of patients with a reduction of 50 percent or more in overall back and leg pain with no increase in pain medications. Non-inferiority (δ=10 percent) followed by superiority were tested in the intention-to-treat population at 3 months (primary analysis) and 12 months (additional prespecified analysis) after the permanent implant. This study is registered with *ClinicalTrials.gov*, NCT02924129.

The applicant stated that standard primary and secondary endpoints for spinal cord stimulation studies were employed. For the primary study endpoint, the study authors defined a responder as having at least 50 percent improvement in pain relative to baseline. The applicant explained that this level of improvement was found to represent a substantial improvement per the IMMPACT recommendations.[71] The study authors stated that the secondary outcomes assessed the percentage change from baseline in leg pain VAS and back pain VAS, prevalence of high responders (≥80 percent reduction) for overall back and leg pain, and prevalence of responders (≥50 percent reduction) for back pain VAS, all at 3 months and 12 months. A host of additional efficacy measures including quality of life, pain medication use, and functional outcomes were also employed as per the IMMPACT recommendations.[72] An independent, blinded Clinical Events Committee (CEC) reviewed and adjudicated all adverse events occurring in the study. The authors reported that, between February 21, 2017 and February 20, 2018, 134 patients were enrolled and randomly assigned (67 to each treatment group), and that there were no between-group differences in the diagnoses, previous treatments, or other baseline demographics or characteristics.[73] The intention-to-treat analysis comprised 125 patients at 3 months (62 in the closed-loop group and 63 in the open-loop group) and 118 patients at 12 months (59 in the closed-loop group and 59 in the open-loop group).

Regarding the applicant's first claim that the closed-loop stimulation of the Evoke® SCS System provides a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications in comparison to open-loop stimulation at 3 and 12 months, the applicant cited findings from this study that a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications was achieved in a greater proportion of patients in the closed-loop group than in the open-loop group at 3 months (82.3 percent vs 60.3 percent; difference 21.9 percent; p=0·0052) and at 12 months (83.1 percent vs 61.0 percent; difference 22.0 percent; p=0·0060). Non-inferiority was met at 3 months (p<0·0001) and 12 months (p<0·0001), as was superiority (3 months, p=0·0052; 12 months, p=0·0060).

Regarding the applicant's second claim that the closed-loop stimulation of the Evoke® SCS System provides a greater percentage change in back pain measured by Visual Analog Scale at 3 and 12 months, the applicant cited Evoke pivotal clinical study findings that at 3 months, 72.1 percent (sd=29.4 percent) of patients in the closed-loop group reported improvements in back pain compared to 57.5 percent in the open-loop group (superiority p=0.015). At 12 months, 69.4 percent (sd=30.6 percent) of patients in the closed-loop group reported improvements in back pain compared versus 54 percent (sd=39.5 percent) in the open-loop group (superiority p=0.020).

Regarding the applicant's third claim that the closed-loop stimulation of the Evoke® SCS System provides a greater incidence of 50 percent reduction in back pain at 3 and 12 months, the applicant cited Evoke pivotal clinical study findings that at 3 months, 81 percent of patients in the closed-loop group reported a 50% or greater reduction in back pain compared to 57 percent in the open-loop group (superiority p=0.0033). Per the study, at 12 months, 80 percent of patients in the closed-loop group achieved this outcome compared to 58 percent in the open-loop group (superiority p=0.0079).

Regarding the applicant's fourth claim that the closed-loop stimulation of the Evoke® SCS System provides a greater incidence of 50 percent reduction in leg pain at 12 months, the applicant cited Evoke pivotal clinical study findings that at 12 months, this outcome was met by a statistically significantly greater proportion of patients in the closed-loop group (83 percent) than in the open-loop group (61 percent) (superiority p=0.0060).

Regarding the applicant's fifth claim that the closed-loop stimulation of the Evoke® SCS System provides a greater incidence of 80 percent reduction in overall back and leg pain at 12 months,

[70] Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, Carlson J, Kim CK, Yang MI, Stauss T, Poree L; Evoke Study Group. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. Lancet Neurol. 2020 Feb;19(2):123–134. Epub 2019 Dec 20.

[71] Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. 2008 Feb;9(2):105–21. Epub 2007 Dec 11.

[72] Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. 2005 Jan;113(1–2):9–19.

[73] Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, Carlson J, Kim CK, Yang MI, Stauss T, Poree L; Evoke Study Group. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. Lancet Neurol. 2020 Feb;19(2):123–134. Epub 2019 Dec 20.

the applicant cited findings from the Evoke pivotal clinical study that at 12 months, this outcome was met by a statistically significantly greater proportion of patients in the closed-loop group (56 percent) than in the open-loop group (37 percent) (superiority p=0.039).

Regarding the applicant's sixth claim that the closed-loop stimulation of the Evoke® SCS System provides consistently greater visual improvement in remaining secondary endpoint measures at 3 and 12 months, the applicant noted the Evoke pivotal clinical study authors observations that significant and clinically important improvements in both treatment groups in all other patient-reported outcomes at 3 and 12 months, including Oswestry Disability Index (ODI), Profile of Mood states Total Mood Disturbance (POMS–TMD), Pittsburgh Sleep Quality Index (PSQI), EQ–5D–5L Index Score, and Short Form Health Survey (SF–12) Physical Component Summary (PCS) and Mental Component Summary (MCS).[74] The authors noted that, in general, the improvement was greater in the closed-loop group than in the open-loop group at both 3 and 12 months, with significant differences seen in POMS–TMD scores (p=0.0037 at 3 months; p=0.0003 at 12 months) and SF–12 MCS scores (p=0.0005 at 3 months) and (p=0.0004 at 12 months).

Regarding the applicant's seventh claim that closed-loop patients spent a greater percentage of time in the therapeutic window compared to open-loop patients, the applicant cited Evoke pivotal clinical study findings that at 3 months, the time in therapeutic window averaged 91.1 percent in the closed-loop group compared to 59.5 percent in the open-loop group (superiority p<0.0001). At 12 months, the time in therapeutic window averaged 95.2 percent in the closed-loop group versus 47.9 percent in the open-loop group (superiority p<0.0001).

Regarding the applicant's eighth claim that the closed-loop stimulation of the Evoke® SCS System provides a balanced safety profile between treatment groups, the applicant cited findings from the Evoke pivotal clinical study that the type, nature, and severity of adverse events were similar between treatment groups. The authors reported that, among the findings, 34 study-related adverse events occurred in 24 patients (23 adverse events in the closed-loop group, in 13 [19 percent] patients [95 percent CI 10.8–30.9], and 11 adverse events in the open-loop group in 11 [16 percent] patients [95 percent CI 8.5–27.5]). The authors stated that the most frequently reported study-related adverse events in both treatment groups were lead migration (nine [7 percent] patients), implantable pulse generator pocket pain (five [4 percent]), and muscle spasm or cramp (three [2 percent]).

The second article provided by the applicant reported the results from the Evoke pivotal clinical study at 24 months follow-up.[75] The applicant submitted this article in support of its claim that the Evoke® SCS System maintained statistical superiority in pain response and pain reduction at 24 months. The authors reported that 50 closed-loop patients and 42 open-loop patients completed 24-month follow-up. The authors noted that the double-blind was maintained for the full study duration. The authors reported that, at 24 months, a significantly greater proportion of closed-loop patients (79.1 percent) were responders (≥50 percent reduction in overall back and leg pain) than open-loop patients (53.7 percent) (p=0.001). Similarly, the authors reported that there was a significantly greater proportion of high responders, (≥80 percent reduction in overall pain) in the closed-loop group (46.3 percent) compared to the open-loop (29.9 percent) (p=0.047). The authors report that reduction in overall back and leg pain was significantly greater for closed-loop patients (mean score=26.4; point decrease=55.6) than open-loop patients (mean score=38.3; point decrease=43.9) (mean score difference=−11.9, p=0.02).

The third article provided by the applicant reported the results from the Avalon study, a prospective, multicenter, single-arm study of the Evoke® SCS System.[76] While not a standalone claim of substantial clinical improvement, the applicant submitted this article in support of its other SCI claims to demonstrate that the relevant findings from the Evoke pivotal trial had been replicated in another multi-center trial with 12-month follow up. The authors of the third article stated that the purpose of the Avalon study was to determine whether maintaining stable SC activation has a beneficial outcome on pain relief by demonstrating the safety and performance of the new closed-loop Evoke® SCS System. The protocol was publicly registered at Australian New Zealand Clinical Trials Registry. Patients were consented at five clinical sites in Australia from August 2015 to April 2017 for the Avalon study.[77] A total of 70 patients underwent a trial procedure. Of these, 68 (97.1 percent) completed the end-of-trial assessments and were evaluable. Of the 68 patients, 56 (82.4 percent) with assessment data had a reduction of 40 percent or more from baseline in their overall VAS rating; of those, 48 patients elected to proceed with a permanent implant. Two additional patients with a segmental VAS reduction of 40 percent or more proceeded with a permanent implant as per the protocol inclusion criterion. Fifty subjects were implanted (71.4 percent of those trialed).

The authors of the Avalon study article stated that baseline assessments in this study included ratings of pain on the Visual Analog Scale (100-mm VAS), impact of pain (Brief Pain Inventory [BPI]), function (Oswestry Disability Index [ODI]), sleep (Pittsburgh Sleep Quality Index [PSQI]), quality of life (EuroQol instrument [EQ–5D–5L]), and medication usage. Adverse events were assessed throughout the study. Along with raw scores and percent change from baseline, VAS data were also analyzed as responders (≥50 percent pain relief) and high responders (≥80 percent pain relief). According to the article, the outcomes data were analyzed using paired t-tests with an alpha of 0.05 and results were presented for the permanently implanted patients only.

The authors reported favorable results for pain relief outcomes.[78] At 12 months, 76.9 percent of patients were back pain responders (≥50 percent pain reduction), with 56.4 percent being classified as high responders (≥80 percent pain reduction). The proportion of patients who were leg pain responders at 12 months was 79.3 percent (≥50 percent pain reduction), and 58.6 percent of patients were high responders (≥80 percent pain reduction). The proportion of patients who were overall pain responders at 12 months was 81.4 percent (≥50 percent pain reduction), and 53.5 percent of

[74] Ibid.

[75] Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, McJunkin T, Carlson J, Kim CK, Yang MI, Stauss T, Pilitsis J, Poree L; Evoke Study Group, Brounstein D, Gilbert S, Gmel GE, Gorman R, Gould I, Hanson E, Karantonis DM, Khurram A, Leitner A, Mugan D, Obradovic M, Ouyang Z, Parker J, Single P, Soliday N. Durability of Clinical and Quality-of-Life Outcomes of Closed-Loop Spinal Cord Stimulation for Chronic Back and Leg Pain: A Secondary Analysis of the Evoke Randomized Clinical Trial. JAMA Neurol. 2022 Jan 8: e214998. doi: 10.1001/jamaneurol.2021.4998. Epub ahead of print. PMID: 34998276; PMCID: PMC8742908.

[76] Russo M, Brooker C, Cousins MJ, Taylor N, Boesel T, Sullivan R, Holford L, Hanson E, Gmel GE, Shariati NH, Poree L, Parker J. Sustained Long-Term Outcomes with Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study. Neurosurgery. 2020 Feb 5. [Epub ahead of print]

[77] Ibid.

[78] Ibid.

patients were high responders (≥80 percent pain reduction).

Based upon the evidence presented by the applicant, we have the following concerns regarding whether the Evoke® SCS System meets the substantial clinical improvement criterion. First, we note that none of the sources provided by the applicant compared the Evoke® SCS System to other currently available technologies, such as other open-loop spinal cord stimulation products. However, in the Evoke pivotal clinical study, all patients were implanted with the Evoke® SCS System, with the difference between study groups being that the implanted devices in the treatment group were set to closed-loop stimulation as opposed to open-loop stimulation. While the study is testing outcomes between different aspects of the Evoke® SCS System itself, additional information comparing the Evoke® SCS System to existing spinal cord stimulators would help inform our assessment of substantial clinical improvement. While the applicant asserted that the Evoke® SCS System is the only available closed-loop SCS, we invite public comment on whether there are other existing technologies which may be appropriate comparators.

Second, we have concern regarding the patient sample size cited in the studies. Furthermore, the applicant cites the Avalon study in Australia to support its claim that the pivotal clinical study's results were replicated internationally. We request additional details about how these two studies' results would be generalizable to the U.S. population.

We are inviting public comments on whether the Evoke® SCS System 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 the Evoke® SCS System would be reported with HCPCS code 63685. To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5465 Level 5 Neurostimulator and Related Procedures, which had a CY 2021 payment rate of $29,444.52 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 63685 had a device offset amount of $24,209.28 at the time the application was received. According to the applicant, the estimated average cost of the Evoke® SCS system is $37,000. We note that the device cost provided by the applicant encompasses the entire Evoke® SCS. However, as previously discussed, the external components of the Evoke® SCS (the surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) may not meet the criteria required under § 419.66(b)(3), *i.e.,* the external components are not implantable and/or do not come in contact with human tissue. Therefore, the cost of only the eligible internal components may be less than the cost of the entire system and could affect the calculations in the following formulas.

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 $37,000 for the Evoke® SCS System is 125.7 percent of the applicable APC payment amount for the service related to the category of devices of $29,444.52 (($37,000/$29,444.52) × 100 = 125.7 percent). Therefore, we believe the Evoke® SCS System meets the first cost significance requirement.

The second cost significance requirement, 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 $37,000 for the Evoke® SCS System is 152.8 percent of the cost of the device-related portion of the APC payment amount for the related service of $24,209.28 (($37,000/$24,209.28) × 100 = 152.8 percent). Therefore, we believe that the Evoke® SCS System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $37,000 for the Evoke® SCS System and the portion of the APC payment amount for the device of $24,209.28 is 43.4 percent of the APC payment amount for the related service of $29,444.52 (((($37,000 − $24,209.28)/$29,444.52) × 100 = 43.4 percent). Therefore, we believe that the Evoke® SCS System meets the third cost significance requirement.

We have a concern regarding whether the Evoke® SCS System meets all of the cost criteria. Specifically, as previously discussed, the external components of the Evoke® SCS may not meet the criteria required under § 419.66(b)(3), *i.e.,* the external components (the surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) are not implantable and/or do not come in contact with human tissue. Therefore, the cost of only the eligible internal components may be less than the cost of the entire system. If the cost of the internal components is sufficiently lower than that of the whole system, then that could affect the calculations for the cost requirements to the point where some of those requirements are not met.

We are inviting public comment on whether the Evoke® SCS System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(5) Pathfinder® Endoscope Overtube

Neptune Medical submitted an application for a new device category for transitional pass-through payment status for the Pathfinder® Endoscope Overtube (the Pathfinder®) for CY 2023. According to the applicant, the Pathfinder® is a flexible, single use, overtube with stiffening capabilities that is used to manage endoscope looping and improve tip control of the endoscope. Per the applicant, the Pathfinder® is indicated for use with an endoscope to facilitate intubation and treatment in the gastrointestinal (GI) tract in adult patients (22 years of age and older). The applicant indicated that the flexible overtube may be connected to vacuum for rigidization. Specifically, the handle includes a vacuum line which is connected to free space within the device that is completely contained, forming the vacuumable volume. The applicant stated that the handle rotator has two positions: the first connects the

vacuumable volume within the device to atmosphere (vent) to stay in the flexible position, and the second position connects the vacuumable volume to a source of vacuum to transition to the rigid condition. When transitioned to the rigid condition, the device maintains its shape at the time of rigidization, allowing the endoscope to advance or withdraw relative to the overtube with minimal disturbance to the surrounding anatomy. According to the applicant, when transitioned to the flexible condition, the device can move relative to the patient anatomy and endoscope for navigation through the GI tract.

With respect to the newness criterion at § 419.66(b)(1), on August 20, 2019, the applicant received 510(k) clearance from FDA for the Pathfinder® as a Class II device to be used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the GI tract in adult patients (22 years of age and older). We received the application for a new device category for transitional pass-through payment status for the Pathfinder® on November 30, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Pathfinder® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Pathfinder® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. The applicant also claimed that the Pathfinder® 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. We are inviting public comments on whether the Pathfinder® meets the eligibility criteria at § 419.66(b).

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.

The applicant provided a list of all established device categories used presently or previously for pass-through payment that describe related or similar products. The applicant indicated that while there are other endoscope overtubes available, there are no known competitive devices on the market that can be toggled from being flexible to rigid instantly to prevent/manage endoscope looping. The applicant stated that the Pathfinder® is unique in its ability to do this using a proprietary technology called Dynamic Rigidization™. For each established device category, the applicant provided explanations as to why that category does not encompass the nominated device: (1) C1748 (endoscope, single-use (*i.e.,* disposable) upper GI, imaging/illumination device (insertable)), and (2) C1749 (endoscope, retrograde imaging/illumination colonoscope device (implantable)). According to the applicant, the Pathfinder® is not an imaging/illumination device. Furthermore, the Pathfinder® can be used in upper and lower GI endoscope/colonoscope procedures to eliminate device looping. As such, the applicant does not believe that the existing codes encompass the Pathfinder®.

Upon review, it does not appear that there are any existing pass-through payment categories that might apply to the Pathfinder®. We are inviting public comment on whether the Pathfinder® meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant states that the Pathfinder® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of the Pathfinder® when used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the GI tract in adult patients (22 years of age and older).

Broadly, the applicant asserts the following areas in which the Pathfinder® would provide a substantial clinical improvement: (1) minimize scope looping and complications from scope looping, (2) reduce endoscopist's workload during endoscope procedure, (3) provide endoscope tip stabilization, (4) enable endoscopic procedure in patients with altered anatomy, (5) enable crossing of anastamosis, and (6) enable antegrade and retrograde enteroscopy, in use for the prevention of endoscope looping. The applicant provided eleven articles specifically for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that the Pathfinder® minimizes scope looping and complications from scope looping, the applicant submitted a prospective single center study performed over 11 months by two endoscopists in the United States.[79] The study population consisted of 15 patients with a mean age of 63.2 years (range 23–88 y) and mean Body Mass Index (BMI) of 28.6 kg/m2 (range 16.8–46.2 kg/m2). Two of the patients were placed under moderate sedation, 11 had monitored anesthesia care (MAC) and two patients underwent general anesthesia. The mean (standard deviation) Boston bowel preparation scale (BBPS) score was 6.9 (1.8), with a range of 6–9. Indications for colonoscopy included surveillance (n=9), evaluation of Crohn's disease (n=2), polyp resection (n=3), and other diagnostic purpose (n=1). To complete the colonoscopy, the endoscopist resorted to the use of the rigidizing overtube in all 15 cases due to several technical difficulties encountered. The authors noted the reasons for overtube use included a history of difficult colonoscopy due to a long, tortuous colon (n=9), inability to reach the cecum (n=3) or the ileocolonic anastomosis (n=1), inability to completely visualize the ileocecal valve (n=1), and inability to advance colonoscope due to looping and bradycardia (n=1). The authors noted that colonoscopy was successfully completed in all 15 cases using the overtube device.

The applicant provided a second article to support the claims that the Pathfinder® minimizes scope looping and complications from scope looping, provides endoscope tip stabilization, enables endoscopic procedure in patients with altered anatomy, and enables crossing of anastomosis. The article consists of an abstract from a set of case studies performed in two tertiary care endoscopy centers in the United

[79] Park, N., Abadir, A., Chahine, A., Eng, D., Ji, S., Nguyen, P., Bernal, E., Simoni, R. & Samarasena, J. B. (2021). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. Techniques and Innovations in Gastrointestinal Endoscopy.

States.[80] From May 2019 to February 2020, 29 patients were consecutively treated using the Pathfinder®. The patients were predominantly male with a median age of 66 years old. Of the 29 patients scoped, one patient received an upper endoscopy, 24 received colonoscopy, and four received enteroscopy. The types of anesthesia provided to these patients included: general anesthesia for four patients, MAC for 15 patients, moderate monitored anesthesia for nine patients, and no sedation for one patient. The indication for using the Pathfinder® was incomplete colonoscopy in 12 patients, enhancing insertion depth not feasible with standard endoscopy in six patients and endoscope stabilization during endoscopic resection in 11 patients, according to the study researchers.

The applicant submitted a third article,[81] which described a 57-year-old male being evaluated for high-risk colon cancer screening due to positive Cologuard, to support the claim that the Pathfinder® minimizes scope looping and complications from scope looping. The applicant pointed out that an initial colonoscopy on the patient was incomplete due to severely redundant colon, *i.e.,* an abnormally long colon with additional loops or twists. The patient was referred to the study's tertiary care center for a repeat attempt with advanced endoscopy. A second colonoscopy was attempted, but significant looping occurred due to the large redundant colon, resulting in another incomplete colonoscopy. Maneuvers like changing to supine position, scope torsion, abdominal pressure, use of colonic overtube and Naviaid balloon-assisted colonoscopy were all unsuccessful, according to the study researchers. The study's tertiary care center performed a virtual computerized tomography (CT) colonography, which revealed a polyp in the ascending colon and markedly redundant colon. This prompted a third colonoscopy, which again showed significant looping of the colon and the colonoscopy was incomplete, per the study researchers. After three unsuccessful conventional colonoscopies, the patient had a colonoscopy with the rigidizing Pathfinder®. According to the study, the exam was technically challenging, requiring more than two hours of procedure time, but was successfully completed.

A fourth article[82] was provided by the applicant to support the claim that the Pathfinder® minimizes scope looping and complications from scope looping. This article presented a challenging case of a laterally spreading tumor at the hepatic flexure in a difficult and unstable colon, which was removed by endoscopic submucosal dissection (ESD) using a novel injectable needle-type knife and with the assistance of the dynamic rigidizing Pathfinder®. The case involved a 66-year-old man with coronary artery disease, hypertension, hyperlipidemia, and diabetes mellitus who was found on screening colonoscopy to have a 35-mm laterally spreading tumor at the hepatic flexure (Paris IIaþIs). An attempted endoscopic mucosal resection was unsuccessful because of non-lifting of the lesion during submucosal injection; therefore, the patient was referred for ESD. Given the length of the procedure and the patient's medical comorbidities, the procedure was performed under general endotracheal anesthesia. A pediatric colonoscope (PCF–H190DL, Olympus America, Center Valley, Pa, USA) with a tapered-tip distal attachment cap (ST hood, Fujifilm Medical Systems, Stamford, Conn, USA) was initially advanced to the cecum and withdrawn to the hepatic flexure. However, because of a highly redundant left colon segment, the colonoscope could not be reduced into a stable, short position for ESD despite manual abdominal counterpressure and position changes. In the looped, long position at the hepatic flexure, the endoscope was noted to be in an extremely unstable position and therefore unsafe for ESD. The dynamic rigidizing Pathfinder® overtube allowed for a stable endoscopic position in a challenging ESD at the hepatic flexure per the applicant.

The applicant provided a fifth article[83] to support the claims that the Pathfinder® minimizes scope looping and complications from scope looping and enables endoscopic procedure in patients with altered anatomy. This article presents two cases demonstrating the utility of the rigidizing overtube in accomplishing altered-anatomy endoscopic retrograde cholangiopancreatography (ERCP), which consisted of the overtube reducing looping and allowing for increased distances that shorter scopes (such as a side-viewing duodenoscope) are unable to achieve. According to the authors, success varies with intubation and cannulation in ERCP for patients with surgically altered anatomy. The authors concluded that this is particularly important in managing gastric loops and tight angulation at surgical anastomoses, including jejunojejunostomy anastomosis.

A sixth article[84] the applicant provided in support of its claim that the Pathfinder® minimizes scope looping and complications from scope looping was a single site case study of a 64-year-old man with a history of C5 spinal cord injury due to a diving accident who presented for screening colonoscopy. A pediatric colonoscope was used initially, but given significant looping, the colonoscope could only reach the transverse colon. The colonoscope was withdrawn, and the Pathfinder® overtube was used. The applicant pointed out that with assistance from the overtube, the colonoscope reached the cecum easily in eight minutes. A 1-cm sessile polyp was found in the ascending colon and was removed by cold snare. An additional 3 polyps measuring less than one centimeter were identified and removed by cold snare, and the procedure was terminated. Three of the polyps (including the 1-cm polyp) were determined to be tubular adenoma. The fourth polyp was identified as a hyperplastic polyp.

A seventh article[85] provided in support of the same claim described a 72-year-old male who presented for surveillance colonoscopy. The colonoscope was successfully advanced to the ascending colon, however, it could not be advanced further due to loop formation. Every time the scope was advanced through the loop the patient became bradycardic to a heart rate in the 40s, presumably from a vasovagal reflex. Repeated attempts at advancing the colonoscope were unsuccessful due to looping and bradycardia despite abdominal counterpressure and position change.

[80] Wei, M. T., Hwang, J. H., Watson, R. R., Park, W., & Friedland, S. (2021). Novel rigidizing overtube for colonoscope stabilization and loop prevention (with video). Gastrointestinal Endoscopy, 93(3), 740–749.

[81] Patel, P., & Khara, H. (2021). S2537 Successful Polypectomy with Novel Rigidizing Overtube with Failed Previous Colonoscopies. Official journal of the American College of Gastroenterology| ACG, 116, S1070.

[82] Coronel, M., Coronel, E., Romero, L., & Phillip, S. G. (2021). Combination of a dynamic rigidizing overtube and a novel injectable needle-type knife to facilitate colorectal endoscopic submucosal dissection. VideoGIE, 6(7), 297–300.

[83] Wei, M. T., Friedland, S., Watson, R. R., & Hwang, J. H. (2020). Use of a rigidizing overtube for altered-anatomy ERCP. VideoGIE, 5(12), 664–666.

[84] Wei, M. T., Hwang, J. H., Watson, R., & Friedland, S. (2020). Use of a rigidizing overtube to complete an incomplete colonoscopy. VideoGIE, 5(11), 583–585.

[85] Abadir, A., Chehade, N. E. H., Park, N., Eng, D., & Samarasena, J. (2020). S1876 Use of a Novel Dynamic Rigidizing Overtube in Difficult Colonoscopy Due to Looping. Official journal of the American College of Gastroenterology| ACG, 115, S971.

The scope was removed and the rigidizing overtube device was introduced onto the scope. The scope with overtube was advanced to the ascending colon in its flexible state. Once in the ascending colon, the overtube was rigidized which allowed for easy cecal intubation and successful completion of colonoscope without any loop formation, as the applicant noted.

An eighth article [86] provided by the applicant in support of the claim of a reduction in the endoscopist's workload during the endoscope procedure was a prospective, single center study performed over 6 months. Difficult colonoscopy subjects were categorized based on looping that prevented reaching the cecum despite position change and abdominal counter pressure (LOOP group), or poor stabilization to perform therapeutic polypectomy (UNSTABLE group). Parameters assessed included successful/failed salvage of the procedure, and the in-procedure National Aeronautics and Space Administration (NASA) Task Load Index (TLX) [87] before and after use of the rigidizing overtube. The TLX raw and weighted scores were compared for each type of demand (mental, physical, effort, temporal, performance, and frustration). Over the study period, there were 14 difficult colonoscopy procedures: eight in the LOOP group and six in the UNSTABLE group. In the LOOP group, all eight cases were salvaged, and cecum was reached after the Pathfinder® overtube was used. The TLX weighted score decreased from 81.1 to 26.0 after use (P,0.01). In the UNSTABLE group, complete polypectomy was successful in all cases using the Pathfinder® overtube. The TLX weighted score decreased from 79.7 to 40.4 after use (P,0.01). In all procedures, the TLX raw scores for each type of demand was reduced. The applicant pointed out that all six dimensions of the NASA–TLX: mental demand, physical demand, temporal demand, effort, performance, and frustration level were significantly improved after using the overtube. All score changes were statistically significant per the study researchers. The overall weighted NASA–TLX score decreased from an average of 80.30 to 30.85 after using the device as the applicant identified. In this case series, the study showed that the novel rigidizing overtube decreases burden on the endoscopist by reducing the workload perceived during the procedure, according to the study researchers.

In support of the claims about a reduction in the endoscopist's workload during the endoscope procedure and enabling antegrade and retrograde enteroscopy, the applicant submitted a ninth article,[88] which was a retrospective single site study over a 6-month period, in which two endoscopists performed retrograde and antegrade enteroscopies using a rigidizing overtube. Retrograde enteroscopy was performed via the anus by advancing the overtube to the cecum in its flexible state with the pediatric colonoscope, reducing the scope and overtube construct, and then rigidizing at the cecum. Following rigidization, the scope was pushed through the ileocecal valve and advanced maximally. Antegrade enteroscopy was performed by inserting the dynamic rigidizing overtube with use of the pediatric colonoscope via the mouth, rigidizing in the duodenum or jejunum, and then advancing maximally. A total of nine retrograde and three antegrade enteroscopies were performed. On retrograde enteroscopy, small bowel depth ranged from 15 cm to 70 cm from the ileocecal valve, with a mean of 48.9 cm. There were no complications associated with use of the dynamic rigidizing overtube, both in antegrade and retrograde evaluation. Of note, in one case, initial attempts at retrograde double-balloon enteroscopy failed due to looping and unfavorable angulation of the ileocecal valve. Multiple attempts at intubation including manual abdominal pressure and position changes were unsuccessful. The dynamic rigidizing overtube was then introduced with successful intubation and subsequent exploration of the ileum. Overall, both endoscopists reported significant ease of enteroscopy compared to traditional double-balloon methods, with lower perceived mental and physical demand, according to the study.

The applicant supplied a tenth article [89] that described a single site case study in support of its claim that the Pathfinder® offers improved endoscope tip stabilization. The study described using a Pathfinder® overtube 85-centimeters long to accommodate a pediatric colonoscope, upper endoscope, or enteroscope. The study presented two contrasting cases demonstrating the rigidizing overtube in colorectal endoscopic submucosal dissection (ESD). In the first case, a 70-year-old man was referred for ESD of a 20mm polyp in the ascending colon. Following submucosal injection, partial circumferential incision was performed. According to the authors, the case was challenging due to poor tip control in the right colon. The cut made by the knife was irregular and of higher risk, requiring more time to make the incision. The polyp was identified as a tubular adenoma with clear margins. In the second case, a 44-year-old man presented following recent diagnosis of ulcerative colitis. Prior colonoscopy demonstrated a large 3–5cm tubulovillous adenoma in the ascending colon. A cap and rigidizing overtube was used during the colonoscopy. During ESD, there was severe fibrosis in the distal portion of the lesion. The rigidizing overtube offered improved scope stability and tip control, facilitating precise dissection of the narrowed fibrotic submucosal space, per the applicant. The lesion was removed en bloc and was identified as a tubular adenoma with low grade dysplasia, with clear margins.

In support of its claim that the Pathfinder® enables endoscopic procedure in patients with altered anatomy, the applicant submitted an eleventh article [90] describing a single site case study about a 42-year-old female with a history of iatrogenic bile duct transection during cholecystectomy who underwent Roux-en-Y Hepaticojejunostomy (HJ). Her course was complicated by HJ stricture requiring double-balloon assisted enteroscopy with ERCP to place a fully covered metal stent. After three months the stent was removed, but restricturing occurred six months later and she developed left-sided intrahepatic stone disease. Double-balloon assisted enteroscopy to reach the anastomosis became more difficult. As a result, multiple antegrade procedures via endoscopic ultrasound (EUS) guided hepaticogastrostomy with lithotripsy were used to treat accessible intrahepatic stones, but several more

[86] Abadir, A., Park, N., Eng, D. J., Chehade, N. E. H., & Samarasena, J. (2020, October). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. American Journal of Gastroenterology (Vol. 115, pp. S83–S83). Two Commerce Square, 2001 Market St., Philadelphia, PA 19103 USA: Lippincott Williams & Wilkins.

[87] TLX @ NASA Ames—Home.

[88] Park, N., Abadir, A., Eng, D., Chehade, N. E. H., & Samarasena, J. (2020). S0972 Enteroscopy Enabled Using a Novel Dynamic Rigidizing Overtube: An Initial Single Center Experience. Official journal of the American College of Gastroenterology| ACG, 115, S495–S496.

[89] Wei, M. T., Hwang, J. H., & Friedland, S. (2021). S2027 Use of the Rigidizing Overtube in Assisting Endoscopic Submucosal Dissection Among Patients with Ulcerative Colitis. Official journal of the American College of Gastroenterology| ACG, 116, S880.

[90] Abadir, A., Park, N., Eng, D. J., Lee, D., & Samarasena, J. (2020). S2330 Altered Anatomy ERCP Using a Novel Dynamic Rigidizing Overtube. Official journal of the American College of Gastroenterology| ACG, 115, S1235.

stones remained. To facilitate further endoscopic procedures, a shortcut was made using laparoscopic revision to create a new entero-enterostomy from the proximal jejunum to the pancreaticobiliary (PB) limb. Repeat enteroscopy with a slim colonoscope failed to enter the PB limb despite multiple attempts due to difficult angulation and looping in the stomach. A rigidizing overtube placed over the colonoscope allowed the scope to advance to the HJ without looping in the stomach and provided improved control up the ascending PB limb. The colonoscope then deployed a stone extraction balloon to remove biliary duct stones. According to the article, this case demonstrates the use of a rigidizing overtube to prevent looping and assist with complex stone removal via ERCP in altered anatomy.

While the applicant has provided articles that describe the clinical use of the Pathfinder® in challenging procedures, the majority of the articles are clinical case series which do not necessarily allow for a clear comparison with common mediation strategies.[91] Additionally, the applicant identified specific procedures for using the Pathfinder® when the physician needs to control looping or enhance endoscope tip control to successfully complete the procedure.[92] The applicant has not provided studies comparing the efficacy of the Pathfinder® with other rigidization devices although the applicant has noted the existence of such devices. Furthermore, all the clinical case study series presented in the applicant's articles were based on small sample sizes. There are other devices available which can help assist the Endoscopist in procedures which are difficult to perform. We have a concern that there has not been adequate comparison to other available devices used for similar indication. We ask for public comment on whether Pathfinder shows superiority over the existing devices/methods used in cases of endoscope looping and abnormal anatomy.

Finally, with respect to the two articles[93] [94] presented to support the substantial clinical improvement claim in reducing endoscopists' workload during endoscopy procedures; in both articles, the authorships were identical for the same study center and time frame, and there were only two participating endoscopists. Therefore, it may be difficult to make comparisons due to the lack of a diverse pool of endoscopists. Additionally, we note that factors such as center and clinical staff characteristics in both studies are difficult to control, and it is difficult to determine if observed differences resulted from the Pathfinder® or from confounding variables. Furthermore, we note there is potential for some level of selection bias if providers are allowed to select the manner and order in which patients are treated, and thereby potentially influence outcomes seen in these studies.

We invite public comments on whether the Pathfinder® 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 the Pathfinder® would be reported with the HCPCS codes listed in Table 37.

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[91] For example, repeat colonoscopy with a different sedation method, different instruments and/or different physicians, double-contrast barium enema, CT colonography, overtube-assisted colonoscopy, double-balloon enteroscopy and colonoscopy, single-balloon enteroscopy, integrated inflated balloon, spiral overtubes, colon capsule endoscopy, C-scan Cap imaging system, and/or robotic colonoscopes). See Franco, D. L., Leighton, J. A., & Gurudu, S. R. (2017). Approach to Incomplete Colonoscopy: New Techniques and Technologies. *Gastroenterology & hepatology, 13*(8), 476–483.

[92] According to the applicant, the Pathfinder® is used for the following procedures: difficult colonoscopy, endoscopic mucosal resection (EMR)/endoscopic submucosal dissection (ESD) of colon, EMR/ESD of the stomach, enteroscopy (both antegrade and retrograde), altered anatomy ERCP, and endoscopic ultrasonography in the colon.

[93] Abadir, A., Park, N., Eng, D. J., Chehade, N. E. H., & Samarasena, J. (2020, October). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. American Journal of Gastroenterology (Vol. 115, pp. S83–S83). Two Commerce Square, 2001 Market St., Philadelphia, PA 19103 USA: Lippincott Williams & Wilkins.

[94] Park, N., Abadir, A., Eng, D., Chehade, N. E. H., & Samarasena, J. (2020). S0972 Enteroscopy Enabled Using a Novel Dynamic Rigidizing Overtube: An Initial Single Center Experience. Official journal of the American College of Gastroenterology|ACG, 115, S495–S496.

TABLE 37: HCPCS CODES REPORTED WITH THE PATHFINDER®

HCPCS Code	Long Descriptor	Status Indicator	APC
Colonoscopy			
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	T	5311
45379	Colonoscopy, flexible; with removal of foreign body(s)	T	5312
45380	Colonoscopy, flexible; with biopsy, single or multiple	T	5312
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance	T	5312
45382	Colonoscopy, flexible; with control of bleeding, any method	T	5312
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	T	5312
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	T	5312
45390	Colonoscopy, flexible; with endoscopic mucosal resection	JI	5313
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures	T	5312
45392	Colonoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures	T	5312
Endoscopy, Small Intestine (Enteroscopy antegrade and retrograde)			
44360	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	J1	5302
44361	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with biopsy, single or multiple	J1	5302
44363	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with removal of foreign body(s)	J1	5302

44364	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
44365	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery	J1	5302
44366	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with control of bleeding (eg, injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)	J1	5302
44369	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique	J1	5302
44370	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with transendoscopic stent placement (includes predilation)	J1	5331
44372	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with placement of percutaneous jejunostomy tube	J1	5302
44373	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with conversion of percutaneous gastrostomy tube to percutaneous jejunostomy tube	J1	5302
44376	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)	J1	5302
44377	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with biopsy, single or multiple	J1	5302
44378	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with control of bleeding (eg, injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)	J1	5302
44379	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with transendoscopic stent placement (includes predilation)	J1	5331

Endoscopic Retrograde Cholangiopancreatography (ERCP)			
43260	Endoscopic retrograde cholangiopancreatography (ercp); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	J1	5303
43261	Endoscopic retrograde cholangiopancreatography (ercp); with biopsy, single or multiple	J1	5303
43262	Endoscopic retrograde cholangiopancreatography (ercp); with sphincterotomy/papillotomy	J1	5303
43263	Endoscopic retrograde cholangiopancreatography (ercp); with pressure measurement of sphincter of oddi	J1	5303
43264	Endoscopic retrograde cholangiopancreatography (ercp); with removal of calculi/debris from biliary/pancreatic duct(s)	J1	5303
43265	Endoscopic retrograde cholangiopancreatography (ercp); with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)	J1	5331
43274	Endoscopic retrograde cholangiopancreatography (ercp); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent	J1	5331
43275	Endoscopic retrograde cholangiopancreatography (ercp); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)	J1	5303
43276	Endoscopic retrograde cholangiopancreatography (ercp); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged	J1	5331
43277	Endoscopic retrograde cholangiopancreatography (ercp); with trans-endoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct	J1	5303
43278	Endoscopic retrograde cholangiopancreatography (ercp); with ablation of tumor(s), polyp(s), or other lesion(s), including pre- and post-dilation and guide wire passage, when performed	J1	5303

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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 $695 for Pathfinder® Endoscope Overtube is 87.57 percent of the applicable APC payment amount for the service related to the category of devices of $793.65 (($695/$793.65) × 100 = 87.57 percent). Therefore, we believe the Pathfinder® Endoscope Overtube meets the first cost significance requirement.

The second cost significance requirement, 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 $695 for the Pathfinder® Endoscope Overtube is 54,724.41 percent of the cost of the device-related portion of the APC payment amount for the related service of $1.27 (($695/$1.27) × 100 = 54,724.41 percent). Therefore, we believe that the Pathfinder® Endoscope Overtube meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $695 for the Pathfinder® Endoscope Overtube and the portion of the APC payment amount for the device of $1.27 is 87.41 percent of the APC payment amount for the related service of $793.65 ((($695 − $1.27)/$793.65) × 100 = 87.41 percent). Therefore, we believe that the Pathfinder® meets the third cost significance requirement.

We are inviting public comment on whether the Pathfinder® Endoscope Overtube meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(6) The Uretero1

STERIS submitted an application for a new device category for transitional pass-through payment status for the Uretero1 for CY 2023. The applicant states that the Uretero1 is a sterile, single-use, disposable digital flexible ureteroscope. According to the applicant, the Uretero1™ Ureteroscope System consists of the following components: (1) the Uretero1, a sterile, single-use flexible disposable digital flexible ureteroscope; and (2) Vision 1, a touch screen camera control unit, with a high-resolution HD imaging system.

Per the applicant, the single use ureteroscope, the Uretero1, consists of: (1) handle, to hold scope (made of polycarbonate, and has no patient contact); (2) articulation lever, an angulated distal tip (polycarbonate 10 percent glass filled, and has no patient contact); (3) handle button, a button to take pictures, video, and zoom live image (made of silicone, and has no patient contact); (4) accessory Port with port cover to prevent backflow during procedures, pass instruments (Makrolon 2458, Indirect/limited patient contact); (5) irrigation port, for fluid access (Makrolon 2458, which has indirect or limited patient contact); (6) flexible shaft (Pebax, made of polyurethane, and has patient contact); (7) shaft strain relief (Santoprene and has contact with limited mucosal membrane); (8) bending/articulation section, which bends the tip of the scope to move the camera (made of stainless-steel compression coils and pull cables and has no patient contact); (9) distal tip, (ABS, and has patient contact); (10) instrument channel (PFA and has indirect and limited patient contact); (11) illumination fiber (made of polymethyl methacrylate (PMMA)/fluorinated polymer and has no patient contact); and (12) the camera (consists of glass and has limited mucosal membrane patient contact), and connector cables and plugs, which have no patient contact.

The Uretero1™ Ureteroscope System is a software-controlled system that consists of the Vision1 (Touch Screen Camera Control Unit (CCU)) and the sterile, single-use high-resolution flexible ureteroscope. Per the applicant, the Uretero1 is inserted to find the causes of problems in the ureters or kidney, and to visualize organs, cavities, and canals in the urinary tract by transurethral or percutaneous access routes. The applicant notes the Uretero1 can also be used with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract, such as kidney stone management (treatment of nephrolithiasis).

According to the applicant, the device is used by urologists during ureteroscopy, a minimally invasive outpatient procedure typically performed under general anesthesia. The applicant states that once the patient is prepped and anesthesia takes effect, the urologist inserts a rigid scope into the urethra, to the bladder to examine the ureteral orifices. Per the applicant, a guidewire is placed through the instrument channel of the rigid scope via fluoroscopic guidance through the orifice, up to the ureter. The applicant states that the rigid scope is removed, and the access sheath is advanced over the inserted guidewire. According to the applicant, the position of the access sheath is confirmed via fluoroscopy, and the obturator is removed from the access sheath, as well as the guidewire (if desired by the surgeon). The applicant states that the flexible ureteroscope is inserted through the access sheath up into the ureters and kidneys. During a procedure, an appropriate sterile solution is passed through the instrument channel of the ureteroscope to fill the bladder to allow greater visibility. If a kidney stone is located (depending on its size), the surgeon will perform laser lithotripsy to fragment the stone into smaller pieces, then remove the fragments.

Per the applicant, the Uretero1 can be used for 4 hours (exceeding the average procedure time of 60 mins), and the device has a timer which notifies the user at three separate intervals of remaining use time: one at 60 minutes, the next at 30 minutes, and the last at 5 minutes of remaining use time. According to the applicant, when the 4 hours of usage time has elapsed, and if the scope is still plugged in, the user will be advised via a message on the screen that a new scope should be inserted and the current ureteroscope will no longer produce a live image. The applicant states that the scope timer only counts down while the device is powered on and plugged in; if it is unplugged, the time stops.

With respect to the newness criterion at § 419.66(b)(1), on November 23, 2021, the applicant received 510(k) clearance from FDA to market the Uretero1 to visualize organs, cavities, and canals in the urinary tract via transurethral or percutaneous access routes. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Uretero1 on March 1, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Uretero1 meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Uretero1 is integral to the service provided, is used for one patient only and comes in contact with human

tissue when it is inserted to visualize organs, cavities, and canals in the urinary tract.[95] Per the applicant, the Uretero1 is reasonable and necessary to diagnose problems in the ureters and kidneys via transurethral or percutaneous access routes. The applicant claims that the Uretero1 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. We are inviting public comments on whether the Uretero1 meets the eligibility criteria at § 419.66(b).

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 the 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. The applicant describes the Uretero1 as a single use, disposable, digital flexible ureteroscope that is used in urologic procedures (ureteroscopy) that diagnose and treat conditions of the urinary tract (*e.g.,* kidney stones, blockage, polyps, abnormal growths, etc.). According to the applicant, a possible existing pass-through code is C1748 (Endoscope, single use (*i.e.,* disposable), upper GI, imaging/illumination device (insertable)), was made effective July 1, 2020.[96] The applicant notes that while this category is for a single use device, it is only appropriate for GI imaging, and more specifically, for endoscopic retrograde cholangiopancreatography (ERCP) procedures. Therefore, the applicant asserts this category would not apply to a single use, disposable, ureteroscope for use in urological procedures. We are inviting public comment on whether the Uretero1 meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant stated that the Uretero1 represents a substantial clinical improvement over existing technology. With respect to this criterion, the applicant submitted studies that examined the impact of the Uretero1 on various diagnostic and therapeutic procedures in the urinary tract.

According to the applicant, the Uretero1 is a single use, disposable, digital flexible ureteroscope that is used in urologic procedures (ureteroscopy) to diagnose and treat conditions of the urinary tract, such as kidney stones, blockages, polyps, and abnormal growths. Broadly, the applicant outlined the following areas for which it claimed the Uretero1 would provide a substantial clinical improvement: (1) prevention of infection transmission, (2) reduced contamination risk, (3) improved deflection performance over reusable ureteroscopes, (4) reduced hospitalization rate and use of antibiotic therapy, (5) reduced complication rate, (6) reduced *post-operative* infection rate, (7) reduced procedure delay, (8) increased patient safety and education, and (9) improved patient outcome when the device is used to perform various diagnostic and therapeutic procedures and treatment in the urinary tract. The applicant provided five articles, an FDA advisory letter, and a set of manufacturer's instructions for cleaning and reprocessing flexible endoscopes specifically for the purpose of addressing the substantial clinical improvement criterion.

The applicant provided a journal pre-proof and two articles to support its claim that the Uretero1 is effective at preventing the transmission of infection. Each of these sources examine the steps required in the complex and time-consuming process to clean and sterilize flexible reusable ureteroscopes so they are fully reprocessed for use. The sources also describe the negative sequelae that follow instances of inefficient and or incomplete device reprocessing. The journal pre-proof of a literature review by Cori Ofstead et al. outlines the steps used to reprocess reusable ureteroscopes.[97] Studies summarized within this literature review described several instances of negative outcomes when ureteroscopes were processed incorrectly or inefficiently. As part of that literature review, Kumarage et al. described an outbreak of *Pseudomonas aeruginosa* later found to be due to an infected flexible reusable ureteroscope that had been used.[98] Fourteen patients of the 40 who were exposed were infected (35 percent attack rate). The root cause of the infected ureteroscopes was attributed to substandard reprocessing of the devices, including processing that was delayed overnight. Kumarage et al. also noted a separate outbreak of a gram-positive cocci which was traced to the use of five ureteroscopes after five patients presented to the ED with urinary tract infections (UTIs) due to the same gram-positive cocci after having each undergone ureteroscopy. Research into the underlying causes and possible sources of the device contamination found that there had been breakdowns in the reprocessing steps.

Another article included in the literature review by Ofstead et al.[99] describes the risks associated with inefficient processing of reusable ureteroscopes using a time-driven activity-based costing (TDABC).[100] This article, by Isaacson et al. (2017), notes the time and costs involved in the decontamination and sterilization processes of reusable flexible ureteroscopes.[101] The authors also measured the time when reprocessing steps were performed inefficiently or were delayed as a result of repairs needed for any damaged ureteroscopes. After following ten ureteroscopes through the reprocessing steps required to fully clean them and determined, via process mapping, that the average reprocessing time was 229.0 ± 74.4 minutes. According to the authors'

[95] Uretero1 Brochure_FINAL.pdf.

[96] Uretero1 Brochure_FINAL.pdf.

[97] Cori L. Ofstead MSPH, Krystina M. Hopkins MPH, Abigail G. Smart MPH, John E. Eiland RNMS, Harry P. Wetzler MD, MSPH, Seth K. Bechis MDMS. Reprocessing effectiveness for flexible ureteroscopes: A critical look at the evidence. Urology (2022), doi: *https://doi.org/10.1016/j.urology.2022.01.033*.

[98] Kumarage J. Khonyongwa K., Khan A., Desai, N., Hoffman P., Taori, SK. Transmission of multidrug resistant *Pseudomonas aeruginosa* between two flexible ureteroscopes and an outbreak of urinary tract infection: The fragility of endoscope decontamination. *J Hosp Infect.* 2019; 102(1):89–94.

[99] Ibid.

[100] TDABC is a process that uses process mapping in conjunction with activity-based costing to calculate and maximize efficiency of complex processes. It was developed by Kaplan and Anderson of the Department of Nephro-Urology, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan.

[101] Isaacson D, Ahmad T, Metzler I, Tzou DT, Taguchi K, Usawachintachit M, Zetumer S, Sherer B, Stoller M, Chi T. Defining the costs of reusable flexible ureteroscope reprocessing using time-driven activity-based costing. J Endourol. 2017;31(10):1026–1031. doi: 10.1089/end.2017.0463. Epub 2017 Sep 20. PMID: 28830223; PMCID: PMC5652038.

calculations, drying the ureteroscopes was the single most time-consuming step and took 126.5 ± 55.7 minutes, and was further dependent on the optimal location and position of the ureteroscopes. Ureteroscopes that needed repair required approximately 143 minutes, causing further delays to availability of the devices.

To further support its claim that the Uretero1 can prevent infection transmission, the applicant cited an April 1, 2021, advisory letter to providers from FDA that outlines concerns about the effectiveness of reprocessing reusable urologic endoscopes.[102] In the letter, FDA confirms it has received over 450 Medical Device Reports (MDRs) describing patient infections associated with reprocessing of reusable devices, which include ureteroscopes. FDA is still investigating these episodes but notes the importance of following manufacturer's instructions for device reprocessing. The applicant also references a report by Grandview Research which notes the market for disposable endoscopes is expected to experience compound growth at a rate of 17 percent between 2022 and 2030, largely due to the growing cross-contamination issue associated with reusable endoscopes.[103] Per the applicant, the projected market growth of disposable cystoscopes, endoscopes, and ureteroscopes is expected to continue to rise over the forecast period due to the advancement in the design of disposable devices and related to the risk of nosocomial infections following ureteroscopy procedures.[104]

To support its second claim that the Uretero1 reduces risk of contamination, the applicant again cited the literature review by Ofstead et al.[105] Referencing the article by Lee et al., titled ''Increasing potential risks of contamination from repetitive use of endoscope,''[106] Ofstead noted that wear and tear of the repeated-use devices contributes to the likelihood that infectious material will remain attached to the device even after reprocessing, as found during Lee et al.'s simulated-use study. Therefore, and per the applicant, the single use Uretero1 eliminates the risk of contamination.

The applicant's third claim with regard to the substantial clinical improvement offered by the Uretero1 is in relation to its improved deflection performance over that of reusable devices. When used in the context of describing ureteroscopes, ''deflection'' refers to the adjustability of the device, which enables the surgeon to see more of the urinary tract.[107] Therefore, improved deflection supports the surgeon's ability to access the kidneys and ureters and perform various diagnostic and therapeutic procedures in the urinary tract. The applicant cited a literature review by Ventimiglia et al. to support its claim.[108] Ventimiglia et al. conducted a literature review on available reusable flexible ureteroscopes and single-use flexible ureteroscopes with a focus on the related costs of each, in terms of performance, maintenance, and reprocessing. As part of its review, Ventimiglia et al. noted that the deflection capability of the Olympus URF–V and Karl Storz Flex-Xc, both single-use flexible ureteroscopes, was equivalent to the deflection capability of reusable flexible ureteroscopes. Ventimiglia et al. did not mention the Uretero1, nor its deflection capability, in the study. Of note, Ventimiglia's literature review referenced the original study by Hennessey et al., which compared the single-use flexible devices with the reusable flexible devices, and which found the performance of the single-use device was equivalent, if not better than the reusable flexible ureteroscopes.[109] The Uretero1 device was not included as a comparison in this study either.

The applicant referred to a study by Bozzini et al.[110] to support its fourth, fifth, and sixth claims that the Uretero1 device demonstrates substantial clinical improvement over existing devices. These claims are that the Uretero1 enables, respectively: reduced hospitalization rate and antibiotic therapy, reduced complication rate, and reduced post-operative infection rate. Using a multicenter, randomized, clinical trial study format, Bozzini et al. enrolled 180 patients who had a renal stone and were scheduled to receive Retrograde Intrarenal Surgery (RIRS) into two groups: Group A (90 patients) underwent treatment with a reusable flexible ureteroscope and Group B (90 patients) (underwent treatment with a disposable flexible ureteroscope). While the outcome of the surgical procedure was not significantly different across the two groups (stone free rates of 86.6 percent for Group A and 90.0 percent for Group B, $p=0.11$), the number of hospitalization days and of antibiotic therapy were higher for Group A ($p \leq 0.05$), those subjects who had been in the reusable flexible ureteroscope trial group. In addition, Group A patients experienced more complications (8.8 percent) than Group B patients (3.3 percent, and with a p=value of ≤0.05), and Group A patients had more major complications. Finally, the overall postoperative infection rate was 16.6 percent for Group A patients compared with 3.3 percent for Group B patients ($p \leq 0.05$). It was noted that none of the Group B patients developed urosepsis, while three patients in Group A developed urosepsis ($p<0.05$).

The applicant referred to an article in *OR Manager* in support of its seventh and ninth claims that the Uretero1 single-use flexible ureteroscope reduces procedure delays and increases patient safety.[111] In addition to the discussion about the introduction of contamination during reprocessing of reusable flexible ureteroscopes, the article notes the high frequency of failures during procedures, resulting in the need for repair. Mathias specifically references a prospective study by Ofstead et al. (2017) conducted at two large healthcare facilities in the Midwest, in which 16 ureteroscopes

[102] Food and Drug Administration. Infections associated with reprocessed urological endoscopes—Letter to health care providers. Published April 1, 2021. Available from: *https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers*.

[103] Grand View Research. ''Disposable Endoscopes Market Size, Share & Trends Analysis Report by Application (Bronchoscopy, ENT Endoscopy), By End-use (Hospitals, Clinics) < By Region (Europe, North America, APAC), and Segment Forecasts, 2022–2030. Published February 2022.

[104] Ibid.

[105] Cori L. Ofstead MSPH, Krystina M. Hopkins MPH, Abigail G. Smart MPH, John E. Eiland RNMS, Harry P. Wetzler MD, MSPH, Seth K. Bechis MDMS. Reprocessing effectiveness for flexible ureteroscopes: A critical look at the evidence. Urology (2022), doi: *https://doi.org/10.1016/j.urology.2022.01.033*.

[106] Lee DH, Kim DB, Kim HY, Baek HS, Kwon SY, Lee MH, Park JC. Increasing potential risks of contamination from repetitive use of endoscope. Am J Infect Control. 2015 May 1;43(5): e13–7. doi: 10.1016/j.ajic.2015.01.017. Epub 2015 Feb 25. PMID: 25726130.

[107] Rajamahanty, S., & Grasso, M. (2008). Flexible ureteroscopy update: indications, instrumentation and technical advances. *Indian journal of urology: IJU: journal of the Urological Society of India, 24*(4), 532–537. *https://doi.org/10.4103/0970-1591.44263*.

[108] Ventimiglia E, Godínez AJ, Traxer O, Somani BK. Cost comparison of single use versus reusable flexible ureteroscope: A systematic review. Turk J Urol 2020; 46(Supp. 1): S40–S45.

[109] Hennessey DB, Fojecki GL, Papa NP, Lawrentschuk N, Bolton D. Single-use disposable digital flexible ureteroscopes: an ex vivo assessment and cost analysis. BJU Int. 2018 May;121 Suppl 3:55–61. doi: 10.1111/bju.14235. PMID: 29656467.

[110] Bozzini G, Filippi B, Alriyalat S, Calori A, Besana U, Mueller A, Pushkar D, Romero-Otero J, Pastore A, Sighinolfi MC, Micali S, Buizza C, Rocco B. Disposable versus Reusable Ureteroscopes: A Prospective Multicenter Randomized Comparison. Res Rep Urol. 2021 Feb 10; 13:63–71. doi: 10.2147/RRU.S277049. PMID: 33604311; PMCID: PMC7882796.

[111] Mathias, JM. ''Greater vigilance needed to combat ureteroscope contamination''. OR Manager: December 2017;(33) 12:1–5.

were cultured and visually inspected after they had been cleaned and sterilized with hydrogen peroxide gas.[112] In this study, 100 percent of the devices were found to have substantial protein contamination, and two had visible bacteria, while others had debris, oily deposits, and residual fluid discoloration.[113] The Mathias article also describes the ''high frequency of damage and repairs'' for reusable flexible ureteroscopes, noting that they then need to be sent out for repairs, resulting in delayed procedures, interrupted workflow, and wasted resources. Per Ofstead, the annual cost per ureteroscope is between $4,000 and $11,000, and findings from the same study showed that the average number of uses between repairs was 19.[114] The Mathias article summarizes the steps that can be taken to reduce risks related to ureteroscope contamination and to focus on patient safety. In addition to following manufacturer's steps for reprocessing the devices, Ofstead suggests the use of single-use endoscopes and accessories which are currently available in the list of recommendations.

Finally, the applicant referenced an FDA advisory letter to health care providers published April 1, 2021, which the applicant stated was released to raise awareness around the risk of infections associated with reprocessing urological endoscopes (*e.g.,* ureteroscopes), although there is no mention of single use ureteroscopes. The applicant pointed to another FDA letter in support of single use duodenoscopes to reduce the risk of infection. The applicant cited these FDA letters in support of its eighth claim that the Uretero1 can be responsible for increased patient education, and patient safety.[115]

In summary, the applicant references these citations to support its assertions that the Utero1 single-use disposable digital flexible ureteroscope presents a substantial clinical improvement over existing devices. We note that many studies included provide details regarding the importance of following established reprocessing guidelines for reusable devices. The evidence provided in the clinical studies emphasizes the risks associated with reprocessing reusable devices. However, none of the studies the applicant includes reference another disposable device as a comparator against which to evaluate and assess the Uretero1. While we find that the source articles provide background about multiple risks associated with reprocessing reusable devices, we would welcome additional evidence demonstrating a comparison of the Uretero1's performance against other similarly disposable devices. We also note that the applicant cited an FDA news release[116] in support of single use duodenoscopes to reduce risk of infection, but this is not the device in question. Additionally, the previously referenced FDA advisory letter[117] regarding ureteroscopes does not mention single-use devices, and it is not clear how the recommendations in the letter support the applicant's claims of substantial clinical improvement related to the use of the Uretero1.

We are inviting public comments on whether the Uretero1 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 the Uretero1 would be reported with the following HCPCS codes listed in Table 38 below.

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[112] Ofstead CL, Heymann OL, Quick MR, Johnson EA, Eiland JE, Wetzler HP. The effectiveness of sterilization for flexible ureteroscopes: A real-world study. Am J Infect Control. 2017 Aug 1;45(8):888–895. doi: 10.1016/j.ajic.2017.03.016. Epub 2017 Jun 15. PMID: 28625700.

[113] Ibid.

[114] Mathias, JM. ''Greater vigilance needed to combat ureteroscope contamination''. OR Manager: December 2017;(33) 12:1–5.

[115] Food and Drug Administration. Infections associated with reprocessed urological endoscopes—Letter to health care providers. Published April 1, 2021. Available from: *https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers.* Accessed August 17, 2021.

[116] Food and Drug Administration. (2019, December 13). *FDA clears first fully disposable duodenoscope, eliminating the potential for infections caused by ineffective reprocessing.* [News release]. Retrieved from *https://www.fda.gov/news-events/press-announcements/fda-clears-first-fully-disposable-duodenoscope-eliminating-potential-infections-caused-ineffective#:~:text=The%20U.S.%20Food%20and%20Drug,and%20other%20upper%20GI%20problems.*

[117] Food and Drug Administration. Infections associated with reprocessed urological endoscopes—Letter to health care providers. Published April 1, 2021. Available from: *https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers.* Accessed August 17, 2021.

TABLE 38: HCPCS CODES REPORTED WITH THE URETERO1

HCPCS Code	Long Descriptor	SI	APC
50575	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with endopyelotomy (includes cystoscopy, ureteroscopy, dilation of ureter and ureteral pelvic junction, incision of ureteral pelvic junction and insertion of endopyelotomy stent)	J1	5375
52344	Cystourethroscopy with ureteroscopy; with treatment of ureteral stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5374
52345	Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5374
52346	Cystourethroscopy with ureteroscopy; with treatment of intra-renal stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5375
52351	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic	J1	5374
52352	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)	J1	5374
52353	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)	J1	5375
52354	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with biopsy and/or fulguration of ureteral or renal pelvic lesion	J1	5375
52355	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic tumor	J1	5375
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, gibbons or double-j type)	J1	5375

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To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5374—Level 4 Urology and Related Services, which had a CY 2021 payment rate of $3,076.34 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 52344 had a device offset amount of $475.29 at the time the application was received. According to the applicant, the cost of the Uterero1 is $1,500.

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 $1,500 for Uretero1 is 48.76 percent of the applicable APC payment amount for the service related to the category of devices of $3,076.34 (($1,500/$3,076.34) × 100 = 48.76 percent). Therefore, we believe the Uretero1 meets the first cost significance requirement.

The second cost significance requirement, 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 $1,500 for Uretero1 is 315.60 percent of the cost of the device-related portion of the APC payment amount for the related service of $475.29 (($1,500/$475.29) × 100 = 315.60 percent). Therefore, we believe that the Uretero1 meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $1,500 for the Uretero1 and the portion of the APC payment amount for the device of $475.29 is 33.31 percent of the APC payment amount for the related service of $3,076.34 ((($1,500 − $475.29)/$3,076.34) × 100 = 33.31 percent). Therefore, we believe that the Uretero1 meets the third cost significance requirement.

We are inviting public comment on whether the Uretero1 meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

B. Proposal to Publicly Post OPPS Device Pass-Through Applications

As noted in section X of this proposed rule, applicants seeking OPPS transitional pass-through status for medical devices (''OPPS device pass-through'') must submit an application to CMS containing certain information.[118] The application is currently undergoing the Paperwork Reduction Act reapproval process, which has notice and comment periods separate from this proposed rule. The 60-day notice was published in the **Federal Register** on April 29, 2022 (87 FR 25488). CMS accepts OPPS device pass-through applications on an ongoing basis throughout the year, but must receive complete applications sufficiently in advance of the first calendar quarter in which OPPS device pass-through status is sought to allow time for analysis, decision-making, and systems changes. In particular, CMS must receive a completed application and all additional information by the first business days in March, June, September, or December of a year for the earliest possible potential pass-through effective dates of July 1, October 1, January 1, or April 1, respectively, of that year. We post complete application information and the timeframes for submitting applications on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment*.

In the CY 2016 OPPS/ASC final rule with comment period, we adopted a policy that beginning in CY 2016, all OPPS device pass-through applications submitted through the quarterly subregulatory process would be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle, including those that were approved upon quarterly review (80 FR 70418). All applications that are approved upon quarterly review are automatically included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review have the option of having their application discussed in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration entirely. We explained that no special reconsideration process would be necessary, as no denial decision would be made except through the annual rulemaking process. Applicants are able to submit new data, such as clinical trial results published in a peer-reviewed journal, for consideration during the public comment process for the proposed rule. We explained that 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.

In the proposed rule, CMS summarizes the information contained in the application, including the applicant's explanation of what the device does, the cost of the device, information about device's FDA approval/clearance, and the applicant's assertions and supporting data on how the device meets the OPPS device pass-through payment criteria under § 419.66. In summarizing this information for inclusion in the proposed rule, CMS restates or paraphrases information contained in the application and attempts to avoid misrepresenting or omitting any of an applicant's claims. CMS also tries to ensure that sufficient information is provided in the proposed rule to facilitate public comments on whether the medical device meets the OPPS device pass-through criteria. Currently, however, CMS does not make the applications themselves, as submitted by the applicants, publicly available.

In the past, CMS has received requests from the public to access and review the OPPS device pass-through applications to further facilitate comment on whether a medical device meets the OPPS device pass-through payment criteria. After considering this issue, we agree that review of the original source information from the applications for OPPS device pass-through status may help to inform public comment. Further, making this information publicly available may foster greater input from experts in the interested party community based on their review of the completed application forms and related materials. Accordingly, as we discuss further in this section, we believe that providing additional information to the public by posting the applications and related materials online may help to further engage the public and foster greater input and insights on the various new medical devices and technologies presented annually for consideration for OPPS device pass-through payment.

We also believe that posting the applications online would reduce the risk that we may inadvertently omit or misrepresent relevant information submitted by applicants, or be perceived as misrepresenting such information, in our summaries in the rules. It also would streamline our evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the device pass-through

[118] The application form, titled ''Process and Information Required to Apply for Additional Device Categories for Transitional Pass-Through Payment Status Under the OPPS,'' describes the process and information required to apply for OPPS device-pass-through status for a medical device and is available on CMS's website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*. Applicants must submit such information as: proposed name or description of additional category; trade/brand names of any known devices fitting the proposed additional category; list of all established categories used presently or previously for pass-through payment that describe related or similar products, along with an explanation as to why the a category does not encompass the nominated device(s); detailed description of clinical uses of each nominated device; a complete description of the nominated devices, including, but not limited to, what it is, what it does, and how it is used; its clinical characteristics; the HCPCS codes for procedures with which it is used; substantial clinical improvement information; sales and marketing information; cost information; FDA approval information; contact information; and other information CMS may require.

applications we receive have been increasing over time. That is, by making the applications available to the public online, we would afford more time for CMS to process and analyze the supporting data and evidence in the applications rather than devoting significant time and resources to summarizing information from the applications in the rule.

Therefore, to increase transparency, enable increased interested party engagement, and further improve and streamline our evaluation process, we propose to publicly post future applications for OPPS device pass-through payment online.[119] Specifically, beginning with applications submitted on or after January 1, 2023, we propose to post online the completed OPPS device pass-through application forms and related materials (*e.g.,* attachments, supportive materials) we receive from applicants. Additionally, we propose to post online information acquired subsequent to the application submission (*e.g.,* updated application information, additional clinical studies, etc.). We propose that we would publicly post all completed application forms and related materials at the same time that the proposed rule is issued, which would afford interested parties the full public comment period to review the information provided by the applicant in its application in conjunction with the proposed rule. We are not proposing to change our policy that applicants whose applications are not approved through the quarterly review process may elect to withdraw their application from consideration in the next applicable rulemaking cycle.

With respect to copyrighted materials, we propose that on the application form itself, the applicant would be asked to provide a representation that the applicant owns the copyright or otherwise has the appropriate license to make all the copyrighted material included with its application public. For any material included with the application that the applicant indicates is copyrighted and/or not otherwise releasable to the public, we propose that the applicant must either provide a link to where the material can be accessed or provide an abstract or summary of the material that CMS can make public, and CMS will then post that link or abstract or summary online, along with the other posted application materials. We invite comments on this proposal.

We note that at times applicants furnish information marked as proprietary or trade secret information along with their applications for OPPS device pass-through payment. Currently, the OPPS device pass-through application instructions specify that data provided in the application may be subject to disclosure and instructs the applicant to mark any proprietary or trade secret information so that CMS can attempt, to the extent allowed under Federal law, to keep the information protected from public view.[120] Consistent with the current application instructions, should an applicant submit such information as part of its application, CMS will attempt, to the extent allowed by Federal Law, to keep this information protected from public view. We emphasize, however, that it is the applicant's responsibility to clearly identify data and information as such in its application.

Additionally, we note that in the past we have received applications in which all the data and information are marked as proprietary or confidential, or certain information, for example, information in support of a claim of substantial clinical improvement, is marked as such. In such cases, we reiterate that we generally would not be able to consider that data and information when determining whether a device meets the criteria for OPPS Device Pass-through payments. Our process provides for public input, so it is important that we provide the information needed for the public to meaningfully comment on the OPPS Device Pass-through payment applications, including the claims applicants make about meeting the OPPS Device Pass-through payment criteria. This proposal would not change the current timeline or evaluation process for OPPS device pass-through payments, the criteria used to assess applications, or the deadlines for various data submissions. Additionally, we do not expect our proposal would place additional burdens on future applicants because we are not proposing to change the information that must be submitted to apply for OPPS device pass-through status, including the supplemental information that could be furnished to support the application. As explained throughout this section, the aim of this proposed policy change is to increase accuracy, transparency, and efficiency for both CMS and interested parties, not to make the OPPS device pass-through process more onerous for applicants.

In connection with our proposal to post the OPPS device pass-through applications online, we expect we would also include less detail in the summaries of the device pass-through applications that we include in the annual OPPS proposed and final rules, given that the public would have access to the submitted applications themselves. We will, however, continue to provide sufficient information in the rules to facilitate public comments on whether a medical device meets the OPPS device pass-through payment criteria. Specifically, we do not anticipate summarizing in significant detail each OPPS device pass-through application in the **Federal Register** as we have in the past, given that the public would have access to the applications under our proposal. In some instances, such as in the discussions of whether devices meet the substantial clinical improvement criterion, we expect to provide a more concise summary of the evidence or a more targeted discussion of the applicant's claims about how that criterion is met based on the evidence and supporting data (although this may vary depending on the application, the medical device, and the nature of the supporting materials provided). We expect that we would continue to generally include, at a high level, the following information in the proposed and final rules: the medical device and applicant name; a description of what the device does; the cost significance calculation; the FDA approval/clearance information; and a summary of the applicant's assertions or claims. We also expect to provide more succinct summaries in the proposed and final rules regarding the applicant's assertions as to how the medical device meets the various OPPS device pass-through criteria under § 419.66. For example, we would include the applicant's assertions as to why the medical device meets the substantial clinical improvement criterion and a list of the sources of data submitted in support of those assertions, along with references to the application in support of this information. In the proposed rule, we would also continue to provide discussion of the concerns or issues we identified with respect to applications submitted. In the final rule, we would continue to provide an explanation of our determination of whether a medical device meets the applicable OPPS device pass-through payment criteria. As noted, we believe the proposal to

[119] CMS is not proposing to make drug and biological pass-through applications public because the nature of the drug and biological application does not necessitate such an action.

[120] See Guidance and Instructions for OPPS Device Pass-Through Applications (Updated 2/1/2022), available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.*

post online the completed application forms and other information described previously would afford greater transparency during the annual rulemaking for purposes of determining whether a medical device is eligible for OPPS device pass-through payment.

We note that if we adopt this proposal in the final rule, we would begin utilizing referring to publicly posted applications in CY 2024 rulemaking cycle, depending on when they are received. This would mean that there would be some OPPS device pass-through applications (those received as of December 31, 2022) that would follow the current process and be described fully in the proposed rule consistent with our historical practice, and other OPPS device pass-through applications (those received after the effective date of January 1, 2023) that would be summarized in the proposed rule with a cross-reference to the publicly posted application, consistent with our new policy. If our proposal is finalized effective January 1, 2023, we would allow applicants that submit an OPPS device pass-through application prior to December 31, 2022 to elect to have the application summarized and publicly posted in lieu of a full CMS write-up. Where applicants do not elect to have applications submitted prior to December 31, 2022 posted publicly and summarized in the proposed rule, we would discuss device pass-through applications in two different ways in the CY 2024 proposed and final rules (either with full write-ups or summaries and cross-references to the publicly posted applications, depending on when the application was submitted). We believe our goals of increasing transparency and ensuring there are sufficient CMS resources to review the increasing numbers of applications are sufficiently important justify use of two approaches for one year if our proposal is finalized. Nonetheless, we also solicit comment on whether we should consider an alternative implementation date of March 1, 2023, which would mean that all OPPS device pass-through applications discussed in the CY 2024 OPPS proposed and final rules would follow the current process and would appear in the rule as a full write-up. Under this alternative approach, CMS would begin publicly posting all OPPS device pass-through applications and summarize and cross-reference the applications beginning in the CY 2025 proposed and final rules consistent with this policy.

We note that for many of the same reasons, we included a similar proposal in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28355 through 28357) that, beginning with applications for FY 2024, we would publicly post online new technology add-on payment applications and certain related materials, as discussed further in that proposed rule. Our goal in making these proposals under both the hospital OPPS and IPPS is not only to increase accuracy, transparency, and efficiency in the device pass-through and new technology add-on payment application review process for both CMS and interested parties, but also to further consistency, where possible, in our procedures and approach for addressing and engaging the public on new technologies in our annual rulemakings.

We are seeking public comment on our proposal to publicly post online the completed OPPS device pass-through application forms and supporting materials and updated application information submitted subsequent to the initial application submission for OPPS device pass-through payment, beginning January 1, 2023.

C. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all 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 utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive procedures 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) and is discussed in detail in section IV.B.3 of this proposed rule. 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).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this 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 for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.B.1.b of this proposed rule 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 no cost/full credit and partial credit devices discussed in sections IV.B.3 and IV.B.4 of this proposed rule.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with

comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- 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
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of 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 or insertion of a device that did 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 was not calculated from claims data; instead, it was applied as a default until claims data were 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 or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a 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. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable

device), temporarily assigning 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 or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a 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 & 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.

As discussed in section X.E of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns regarding CY 2020 data as a result of the COVID–PHE, we adopted a policy to use CY 2019 claims data to establish CY 2022 prospective rates. While we believed CY 2019 represented the best full year of claims data for ratesetting for CY 2022, we stated that our policy of temporarily assigning a higher offset percentage if warranted by additional information would provide a more accurate device offset percentage for certain procedures. Specifically, for procedures that were assigned device-intensive status, but were assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically-similar code in the absence of CY 2019 claims data, we adopted a policy to assign device offset percentages for such procedures based on CY 2020 data if CY 2020 claims information is available.

For CY 2023, consistent with our broader proposal to use CY 2021 claims for CY 2023 OPPS and ASC ratesetting purposes and our historical practice, we propose to use CY 2021 claims information for determining device offset percentages and assigning device-intensive status.

The full listing of the proposed CY 2023 device-intensive procedures can be found in Addendum P to this proposed rule (which is available via the internet on the CMS website).

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined 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. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019

and subsequent years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''.

We are not proposing any changes to this policy for CY 2023.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced 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 policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a 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 the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices for CY 2023.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout the 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 the proposed rule includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined under section 351 of the PHS 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 for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not

being paid for as an HOPD service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2023 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 website).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this 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 our website 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 our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Transitional Pass-Through Payment Period for 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 drug or biological 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 approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a drug's or biological's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2022

There are 32 drugs and biologicals for which pass-through payment status expires on December 31, 2022 or for which the equitable adjustment to mimic continued pass-through payment will end on December 31, 2022, as listed in Table 39. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of January 1, 2019 through December 31, 2022. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals 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.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63755 through 63756), we also recognized the effects of the Public Health Emergency (PHE) on drugs and biologicals whose pass-through payment status expired or expires between December 31, 2021, and September 30, 2022, by adopting a one-time equitable adjustment under section 1833(t)(2)(E) of the Act to continue separate payment for the remainder of CY 2022 to mimic continued pass-through status for that year. Because pass-through payment status can expire at the end of a quarter, we finalized that the adjusted payment would be made for between one and four quarters, depending on when the pass-through period expires for the drug or biological. For a detailed discussion of the equitable adjustment for drugs with expiring pass-through status in CY 2022, we refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63755 through 63756).

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 $135 for CY 2023), as discussed further in section V.B.1 of this proposed rule). 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 propose to provide separate payment at the applicable ASP-based payment amount (which is proposed at ASP+6 percent for non-340B drugs for CY 2023 and

subsequent years), as discussed further in section V.B.2 of this proposed rule.

Refer to Table 39 for the list of drugs and biologicals for which pass-through payment will expire or for which separate payment to mimic pass-through payment status will end on December 31, 2022. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of this proposed rule (which is available via the internet on the CMS website).

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TABLE 39: DRUGS AND BIOLOGICALS FOR WHICH PASS - THROUGH PAYMENT STATUS OR SEPARATE PAYMENT TO MIMIC PASS-THROUGH PAYMENT WILL END ON DECEMBER 31, 2022

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through or *Adjusted Mimicked Pass-Through Payment End Date
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9182	01/01/2019	12/31/2022*
J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2022*
J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2022*
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2022*
J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2022*
J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2022*
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	12/31/2022*
J0642	Injection, levoleucovorin (khapzory), 0.5 mg	G	9334	01/01/2020	12/31/2022
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	12/31/2022*
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	12/31/2022*

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through or *Adjusted Mimicked Pass-Through Payment End Date
J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	12/31/2022*
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	12/31/2022*
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	12/31/2022*
J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	12/31/2022*
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	12/31/2022*
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	12/31/2022*
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	12/31/2022*
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	12/31/2022*
C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	12/31/2022*
J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	12/31/2022*
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	12/31/2022*
J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	12/31/2022*
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	12/31/2022*
J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	12/31/2022*
J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	12/31/2022*
J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	12/31/2022*

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through or *Adjusted Mimicked Pass-Through Payment End Date
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	12/31/2022*
J0691	Injection, lefamulin, 1 mg	G	9332	01/01/2020	12/31/2022
J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022

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4. Proposed Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2023

We propose to end pass-through payment status in CY 2023 for 43 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2020 and January 1, 2021, are listed in Table 40. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2023, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status, are assigned status indicator ''G'' only for the duration of their pass-through status as shown in Table 40.

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 2023, we propose 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 2023. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP+6 percent. Therefore, we propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2023 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 also 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 propose that their pass-through payment amount would be equal to ASP+6 percent for CY 2023 minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6 of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We propose to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2023 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 payment 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 2023, consistent with our CY 2022 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier,

for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2023, we propose 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 propose to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b of this proposed rule), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b of this proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP. We refer readers to Table 40 below for the list of drugs and biologicals for which we propose to expire pass-through payment status during CY 2023.

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TABLE 40: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS PROPOSED TO EXPIRE DURING CY 2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
J0223	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
J0791	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
J1201	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4	G	9362	07/01/2020	06/30/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		mg and relebactam 2 mg				
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J1738	J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
J3032	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
J3241	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J7402	J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-	G	9350	07/01/2020	06/30/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		qyyp, biosimilar, (trazimera), 10 mg				
Q5118	Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
A9591	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9067	C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9144	J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
J9227	J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
J9281	J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9317	J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
J9318	J9318	Injection, romidepsin, non-lyophilized, 0.1 mg	G	9428	10/01/2020	09/30/2023
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
J0699	J0699	Injection, cefiderocol, 10 mg	G	9380	01/01/2021	12/31/2023
J1437	J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
A9592	A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1427	J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
J1554	J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
J9037	J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
J9223	J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
J9316	J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
J9349	J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
Q2053	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023

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5. Proposed Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing in CY 2023

We propose to continue pass-through payment status in CY 2023 for 32 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2021, and April 1, 2022, are listed in Table 41. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2022, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

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 2023, we propose 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 2023. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in section V.B.1.c under the CY 2023 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 propose that their pass-through payment amount would be equal to ASP+6 percent for CY 2023 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6 of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We propose to continue to update pass-through payment rates on a quarterly basis on our website during CY 2023 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 payment 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 2023, consistent with our CY 2022 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2023, we propose 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 propose to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b of this proposed rule), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b of this proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we propose would have pass-through payment status expire after December 31, 2023, are shown in Table 41.

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TABLE 41: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS PROPOSED TO EXPIRE AFTER CY 2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0224	J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024

J1448	J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024
J9353	J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413	07/01/2021	06/30/2024
C9081	Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422	10/01/2021	09/30/2024
C9082	J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
C9083	J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
C9084	J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205	10/01/2021	09/30/2024
J1823	J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024

C9087	J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024
J9021	J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
N/A	A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
N/A	C9085	Injection, avalglucosidase alfa-ngpt, 2 mg	G	9433	01/01/2022	12/31/2024
N/A	C9086	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
N/A	J0248	Injection, remdesivir, 1 mg)	G	9200	04/01/2022	03/31/2025
N/A	J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
N/A	C9092	Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
N/A	C9093	Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
N/A	C9091	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
N/A	C9090	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
N/A	J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025
N/A	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025

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6. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals To Offset Costs Packaged Into APC Groups

Under the regulation at 42 CFR 419.2(b)(15), 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 the regulation at 42 CFR 419.2(b)(16), 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. Finally, under the regulation at 42 CFR 419.2(b)(4), anesthesia drugs are packaged in the OPPS. 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 policy-packaged drugs, which include 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 2023, as we did in CY 2022, we propose 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 42.

TABLE 42: PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2023

CY 2023 APC	CY 2023 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 propose to continue to post annually on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

B. 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 $130 for CY 2022 (86 FR 63635 through 63637).

Following the CY 2007 methodology, for this proposed rule, we use 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 2023 and rounded the resulting dollar amount ($133.73) to the nearest $5 increment, which yielded a figure of $135. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS's Office of the Actuary. Based on these calculations using the CY 2007 OPPS methodology, we propose a packaging threshold for CY 2023 of $135. b. Proposed Packaging of Payment for HCPCS Codes that Describe Certain Drugs, Certain Biologicals, and Certain Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

To determine the proposed CY 2023 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 that had a HCPCS code in CY 2021 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2021 claims processed through June 30, 2021, 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 propose to continue to package in CY 2023: 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 2023, we use 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 propose for separately payable drugs and biologicals (other than 340B drugs)) for CY 2023, as discussed in more detail in section V.B.2.b of this proposed rule) to calculate the CY 2023 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2021 (data that were used for payment purposes in the physician's office setting, effective April 1, 2022) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2023, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2021 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 website) 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, 2022. 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 2021 hospital claims data to determine their per day cost.

We propose to package items with a per day cost less than or equal to $135 and identify items with a per day cost greater than $135 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2021 HCPCS codes that were reported to the CY 2022 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2023.

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 proposed rule, we propose to use ASP data from the fourth quarter of CY 2021, 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, 2022, along with updated hospital claims data from CY 2021. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the final rule with comment period will be based on ASP data from the second quarter of CY 2022. 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, 2022. These payment rates would then be updated in the January 2023 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2023. For items that do not currently have an ASP-based payment rate, we propose to recalculate their mean unit cost from all of the CY 2021 claims data and updated cost report information available for the CY 2023 OPPS/ASC 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 drugs' HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we propose 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 costs fluctuate relative to the proposed CY 2023 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2022. 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 2023, consistent with our historical practice, we propose to apply the following policies to those 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 2022 and that are proposed for separate payment in CY 2023, and that then have per day costs equal to or less than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would continue to receive separate payment in CY 2023.
- HCPCS codes for drugs and biologicals that were packaged in CY 2022 and that are proposed for separate payment in CY 2023, and that then have per day costs equal to or less than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would remain packaged in CY 2023.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2023 but that then have per-day costs greater than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would receive separate payment in CY 2023.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe 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 propose 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 2023.

For CY 2023, 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 2021 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 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 2021 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); 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 if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2023 drug packaging threshold of $135 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2023 drug packaging threshold of $135 (in which case 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 2023 is displayed in Table 43.

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TABLE 43: PROPOSED HCPCS CODES TO WHICH THE CY 2023 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2023 HCPCS Code	CY 2023 Long Descriptor	CY 2023 Status Indicator (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
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

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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 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 for purposes of paragraph (14). We refer to this alternative methodology as the ''statutory default.'' Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[121]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we propose to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2022.

b. CY 2023 Proposed Payment Policy

For CY 2023 and subsequent years, we propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We formally propose to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described in section V.B.6 of this proposed rule). We refer readers to section V.B.6. for a full discussion of our proposed CY 2023 payment policy for 340B drugs.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). For CY 2020 and subsequent years, we adopted a policy to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) (84 FR 61318 and 85 FR 86039). For CY 2023 and subsequent years, we propose to continue to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also propose to apply this provision to non-SCOD separately payable drugs. Because we propose to establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. We propose, if finalized, our proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, we formally propose that the payment amount for these drugs (in this case, as a rate of WAC minus 22.5 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy. We also refer readers to section V.B.6. for a full discussion of our proposed CY 2023 payment policy for 340B drugs.

Consistent with our current policy, we propose for CY 2023 and subsequent years that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also propose that the budget neutral weight scalar would not be applied in

[121] 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.*

determining payments for these separately payable drugs and biologicals.

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 website), which illustrate the proposed CY 2023 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, 2022, or WAC, AWP, or mean unit cost from CY 2021 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 2023 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2023 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2022 (July 1, 2022, through September 30, 2022) will be used to set the payment rates that are released for the quarter beginning in January 2023 in December 2022. 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 2022, are based on mean unit cost in the available CY 2021 claims data. If ASP information becomes available for payment for the quarter beginning in January 2023, 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 2022 ASP data) that do not have ASP information available for the quarter beginning in January 2023. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2021 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2023 payment purposes and are only illustrative of the CY 2023 OPPS 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 (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we finalized a policy to implement separate HCPCS codes for biosimilar biological products that was based on the policy established in the CY 2018 PFS final rule. The policy we established allowed all biosimilar biological products to be eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367).

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. Accordingly, in the CY 2019 OPPS/ASC final rule (83 FR 58977), we implemented a policy that for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

For CY 2023 and subsequent years, we propose to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also formally propose to continue our current policy of paying for nonpass-through biosimilars acquired under the 340B program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. We refer readers to section V.B.6. for a full discussion of our proposed CY 2023 payment policy for 340B drugs.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2023 and subsequent years, we propose to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2023. Therefore, we propose for CY 2023 and subsequent years to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). For CY 2023 and subsequent years, we also propose to rely on the most recently available mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2023 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available via the internet on the CMS website).

4. Proposed Payment for Blood Clotting Factors

For CY 2022, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (86 FR 63643). That is, for CY 2022, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2022 updated furnishing fee was $0.239 per unit.

For CY 2023 and subsequent years, we propose 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 a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update 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 PFS and OPPS/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 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

We propose to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

5. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

For CY 2023 and subsequent years, we propose to continue to use the same payment policy as in CY 2022 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2023 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the internet on the CMS website.

6. OPPS Payment Methodology for 340B Purchased Drugs

a. Overview

Under the OPPS, we generally set payment rates for separately payable drugs and biologicals under section 1833(t)(14)(A). Section 1833(t)(14)(A)(iii)(II) provides that, if hospital acquisition cost data is not available, the payment amount is the average price for the drug in a year established under section 1842(o), which cross-references section 1847A, which generally sets a default rate of ASP+6 percent for certain drugs. The provision also provides that the average price for the drug in the year as established under section 1847A is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program.

This policy has been the subject of significant litigation, recently culminating in the Supreme Court's decision in *American Hospital Association* v. *Becerra,* No. 20–1114, 2022 WL 2135490 (June 15, 2022). Originally, in December 2018, the United States District Court for the District of Columbia (the ''District Court'') concluded that the Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals. The agency then appealed to the United States Court of Appeals for the District of Columbia Circuit (hereinafter referred to as ''the D.C. Circuit''), and on July 31, 2020, the court entered an opinion reversing the District Court's judgment in this matter. Plaintiffs then petitioned the United States Supreme Court for a writ of certiorari, which was granted on July 2, 2021.[122]

On June 15, 2022, the Supreme Court reversed the decision of the D.C. Circuit, holding that HHS may not vary payment rates for drugs and biologicals among *groups of hospitals* under section 1833(t)(14)(A)(iii)(II) in the absence of having conducted a survey of hospitals' acquisition costs under subparagraph (t)(14)(A)(iii)(I). While the Supreme Court's decision concerned payment rates for CYs 2018 and 2019, it obviously has implications for CY 2023 payment rates. However, given the timing of the Supreme Court's decision, we lacked the necessary time to incorporate the adjustments to the proposed payment rates and budget neutrality calculations to account for that decision before issuing this proposed rule, as explained further below. For that reason alone, the payment rates, tables, and addenda in this proposed rule reflect a payment rate of ASP minus 22.5 percent for drugs and biologicals acquired through the 340B program for CY 2023, consistent with our prior policy. However, we are also providing 340B Alternate supporting files, which provide information regarding the effects of removing the 340B program payment policy for CY 2023. We fully anticipate applying a rate of ASP+6 percent to such drugs and biologicals in the final rule for CY 2023, in light of the Supreme Court's recent decision. We are still evaluating how to apply the Supreme Court's recent decision to prior cost years.

Each year since 2018, we have continued our policy of paying for drugs and biologicals acquired through the 340B Program at ASP minus 22.5 percent. When we were developing this proposed rule, we intended to propose to continue our 340B policy, which was upheld by the D.C. Circuit Court of Appeals. That is, the rates that we previously developed, the tables, and the addenda that are part of this proposed rule build on the policy that had been in effect since 2018, which

[122] *https://www.supremecourt.gov/orders/courtorders/070221zor_4gc5.pdf.*

paid for drugs and biologicals at one rate if they were acquired through the 340B program (ASP minus 22.5 percent), and at another rate if they were not acquired through the 340B program (ASP+6 percent).

Development of the annual OPPS proposed rule begins several months before publication. This process includes formulating proposed policies and calculating proposed rates, which then must be adjusted to maintain budget neutrality. In particular, section 1833(t)(9)(B) requires that if the Secretary makes adjustments under subparagraph (A) of that section to the groups, the relative payment weights, or the wage or other adjustments, those adjustments for the year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures that would have been made absent those adjustments. When the Supreme Court's decision was issued on June 15, 2022, we had already developed the policies we intended to include in the proposed rule and calculated the payment rates, which included application of an adjustment to maintain budget neutrality. There was not sufficient time remaining in the proposed rule development process for us to change the policy and accompanying rates in response to the Supreme Court's decision. The OPPS is a calendar year payment system and to ensure OPPS payment rates and policies are effective on January 1, 2023, we must issue the final rule with comment period in early November to allow for the 60-day delayed effective date that the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)) requires for major rules. We generally attempt to issue the annual OPPS/ASC proposed rule by early July to ensure that there is sufficient time to allow for the 60-day public comment period required by section 1871(b)(1) of the Act, followed by review of public comments and development of the final rule in time for the early November issuance date. If we were to change the policy and accompanying rates in response to the Supreme Court's decision, the proposed rule would be substantially delayed, which would jeopardize our ability to develop the final rule in time to meet the early November deadline required to adhere to the CRA's 60-day delayed effective date requirement. Therefore, the rates, tables, and addenda in this proposed rule reflect the proposal to pay for drugs differently if they were acquired through the 340B program, namely at ASP minus 22.5 percent, with the anticipated savings redistributed to all other items and services in a budget neutral manner. If interested parties or members of the public wish to comment on the propriety of maintaining differential payment for 340B-acquired drugs in the future, or other aspects of these as-published rates, we will consider such comments, subject to the constraints of the Supreme Court's recent decision.

That said, as we noted earlier, in light of the Supreme Court's decision in *American Hospital Association,* we fully anticipate reverting to our prior policy of paying ASP+6 percent, regardless of whether a drug was acquired through the 340B program. We advise readers that a reversion to that policy will have an effect on the payment rates for other items and services due to the budget neutral nature of the OPPS system. To maintain OPPS budget neutrality under our anticipated final policy where non-pass-through separately payable OPPS drugs purchased under the 340B program are paid at ASP+6 percent in CY 2023, we would need to determine the change in estimated OPPS spending associated with the alternative policy. Based on separately paid line items with the ''JG'' modifier in the CY 2021 claims available for OPPS ratesetting, which represent all drug lines for which the 340B program payment policy applied, the estimated payment differential would be an increase of approximately $1.96 billion in OPPS drug payments. To ensure budget neutrality under the OPPS after applying this alternative payment methodology for drugs and biologicals purchased under the 340B Program, we would apply this offset of approximately $1.96 billion to decrease the OPPS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor, for a revised conversion factor of $83.279. This is a similar application of OPPS budget neutrality as originally applied to the OPPS 340B program payment policy described in the CY 2018 OPPS final rule (82 FR 59258, 82 FR 59482 through 59484). In the CY 2018 OPPS final rule, this budget neutrality adjustment increased the conversion factor to budget neutralize the decreased spending for drugs acquired through the 340B program in CY 2018. Under our anticipated final policy, we would apply that same calculation but we would decrease the conversion factor to budget neutralize the increased spending associated with payments for drugs acquired through the 340B program that would result from increasing the rate of ASP minus 22.5 percent to ASP+6 percent. We note that the amount of this adjustment would potentially change in the final rule due to updated data, potential modifications to the estimate methodology, and other factors. A table detailing the impact on hospital outpatient payment rates of removing the payment differential for 340B drugs and the corresponding budget neutrality adjustment for CY 2023 is included in the 340B Alternative supporting files.

b. Payment for 340B Drugs and Biologicals in CYs 2018 Through 2022

For full descriptions of our OPPS payment policy for drugs and biologicals acquired under the 340B program, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649).

Our policies for 340B-acquired drugs have been the subject of ongoing litigation, the procedural history of which is generally described above. On December 27, 2018, in the case of *American Hospital Association, et al.* v. *Azar, et al.,* the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.

On July 10, 2019, the district court entered final judgment. The agency appealed to the D.C. Circuit, and on July 31, 2020, the court entered an opinion reversing the district court's judgment in this matter. In January of 2021, appellees petitioned the United States Supreme Court for a writ of certiorari. On July 2, 2021, the Supreme Court granted the petition and heard oral arguments in November 2021. And, as noted above, the Supreme Court reversed the decision of the D.C. Circuit.

Before the D.C. Circuit upheld our authority to pay ASP minus 22.5 percent for 340B drugs, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the CY 2020 OPPS/ASC proposed rule was issued, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters in CY 2018 and 2019.

We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for years going forward, and also may be used to devise a remedy for prior years if the district court's ruling was upheld on appeal. The district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available.[123] No 340B hospital disputed in the rulemakings for CY 2018 and 2019 that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B program, which is significant because 340B hospitals have internal data regarding their own drug acquisition costs. We stated in the CY 2020 OPPS/ASC final rule with comment period that we thus anticipated that survey data collected for CY 2018 and 2019 would confirm that the ASP minus 22.5 percent rate is a conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program. We also explained that a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion. For a complete discussion of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs, we refer readers to the CY 2021 OPPS/ASC proposed rule (85 FR 48882 through 48891) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055). We proposed a net payment rate for 340B drugs of ASP minus 28.7 percent (minus 34.7 percent plus 6 percent) based on survey data, and also proposed in the alternative that the agency could continue its current policy of paying ASP minus 22.5 percent for CY 2021. On July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that this interpretation of the statute was reasonable.

During CY 2021 rulemaking, based on feedback from interested parties, we stated that we believed maintaining the policy of paying ASP minus 22.5 percent for 340B drugs was appropriate to maintain consistent and reliable payment for these drugs to give hospitals increased certainty as to payments for these drugs. For CY 2022, we continued this 340B policy without modification as described in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63648).

[123] *See American Hosp. Assoc.* v. *Azar,* 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

We are still evaluating how to apply the Supreme Court's recent decision to cost years 2018–2022. In that decision, the Court summarized the parties' arguments regarding budget neutrality and stated that, ''[a]t this stage, we need not address potential remedies.'' We are additionally interested in public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018–2022 given that the Court did not resolve that issue.

c. CY 2023 Proposed 340B Drug Payment Policy

As discussed above, given the timing of the Supreme Court's decision in *American Hospital Association* v. *Becerra,* we lacked the necessary time to account for that decision before issuing this proposed rule. For that reason alone, for CY 2023, we formally propose at this time to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. But again, in light of the Supreme Court's decision, we fully anticipate adopting, in the final rule, a policy of paying ASP+6 percent for 340B-acquired drugs and biologicals. This formal proposal is in accordance with the policy choices and calculations that CMS made in the months leading up to publication of this proposed rule before the Supreme Court issued its decision in *American Hospital Association* v. *Becerra,* No. 20–1114, 2022 WL 2135490 (June 15, 2022). We propose, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs and biologicals (assigned status indicator ''K''), other than vaccines and drugs on pass-through status, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. We formally propose to continue our current policy for calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

We also formally propose to continue the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. The 340B-acquired drugs that are priced using AWP would continue to be paid an adjusted amount of 69.46 percent of AWP. Additionally, we propose to continue to exempt rural sole community hospitals (as described under the regulations at § 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment.

We also formally propose continuing to require hospitals to use modifiers to identify 340B-acquired drugs. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and the requirements for use of modifiers ''JG'' and ''TB''.

Again, we note that, in light of the Supreme Court's recent decision in *American Hospital Association,* we fully anticipate reverting to our prior policy of paying for drugs at ASP+6 percent, regardless of whether they were acquired through the 340B program for CY 2023. We also fully expect that when we revert to paying for drugs acquired through the 340B program at ASP+6 percent, we will budget neutralize that increase consistent with the OPPS statute and our longstanding policy by making a corresponding decrease to the conversion factor to account for the increase in the payment rates for these drugs. As set forth above, to ensure budget neutrality under the OPPS, after applying this alternative payment methodology for drugs and biologicals purchased under the 340B Program, we currently estimate that we would apply an offset of approximately $1.96 billion to decrease the OPPS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor, for a revised conversion factor of $83.279.

Public comments on the budget neutrality adjustment are welcome and will be carefully considered. For a more detailed discussion of the budget neutralizing effects of reverting to this prior policy of paying for all drugs (whether 340B-acquired or not) at ASP+6 percent, please see the 340B Alternative supporting files, which include an alternative impact table, the calculation of a 340B Alternative conversion factor, the budget neutrality factors associated with the 340B Alternative policy, and Addenda A, B, and C, all of which provide information regarding the effects of removing the 340B program payment policy for CY 2023.

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we

unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package 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). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described earlier 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 2022, the payment rate for APC 5053 (Level 3 Skin Procedures) was $596.39, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,774.73, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $3,326.39. This information is also available in Addenda A and B of the CY 2022 final rule with comment period, as issued with the final rule correction notice (87 FR 2058) (the correction notice and corrected Addenda A and B are available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we propose to continue it for CY 2023. Under the current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years, we adopted a policy where we determined the high cost/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. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high cost group. In addition, we assigned any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group (85 FR 86059).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. 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 over $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it did not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). For more detailed information and discussion regarding the goals of this policy and the subsequent comment solicitations in CY 2019 and CY 2020 regarding possible alternative payment methodologies for graft skin substitute products, please refer to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347); CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 to 58968); and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61328 to 61331).

b. Proposals for Packaged Skin Substitutes for CY 2023

For CY 2023, consistent with our policy since CY 2016, we propose to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPS/ASC through CY 2018

OPPS/ASC final rules with comment period, we analyzed CY 2019 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 2023 MUC threshold is $47 per cm^2 (rounded to the nearest $1) and the proposed CY 2023 PDC threshold is $837 (rounded to the nearest $1). We want to clarify that the availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2023, as we did for CY 2022, we propose to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we propose to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group except that we propose that any skin substitute product that was assigned to the high cost group in CY 2022 would be assigned to the high cost group for CY 2023, regardless of whether it exceeds or falls below the CY 2023 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2023, we propose to continue to assign skin substitutes with pass-through payment status to the high cost category. We propose 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 propose to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we propose to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We propose to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b of this proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2023 MUC and PDC thresholds. 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).

In the CY 2023 PFS proposed rule, which will be included in the July 29, 2022 **Federal Register**, there is a proposal to treat all skin substitute products consistently across healthcare settings as incident-to supplies described under section 1861(s)(2) of the Act. If this proposed policy is finalized, manufacturers would not report ASPs for skin substitute products starting in CY 2023; and we would no longer be able to use ASP+6 percent pricing for a graft skin substitute product to determine whether the product should be assigned to the high cost group or the low cost group. However, manufacturers would continue to report WAC and AWP pricing information for skin substitute products through pricing compendia. Having WAC and AWP pricing will allow us to continue to use our alternative process to assign graft skin substitute products to the high cost group when cost data for a product is not available.

Table 44 includes the final CY 2023 cost category assignment for each skin substitute product.

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TABLE 44: PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2023

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	Proposed CY 2023 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	N/A	Low
A2002	Mirragen adv wnd mat per sq	N/A	Low
A2005	Microlyte matrix, per sq cm	N/A	Low
A2006	Novosorb synpath per sq cm	N/A	Low
A2007	Restrata, per sq cm	N/A	High
A2008	Theragenesis, per sq cm	N/A	Low
A2009	Symphony, per sq cm	N/A	Low
A2010	Apis, per square centimeter	N/A	Low
A2011	Supra sdrm, per sq cm	N/A	Low
A2012	Suprathel, per sq cm	N/A	Low
A2013	Innovamatrix fs, per sq cm	N/A	Low
A4100	Skin sub fda clrd as dev nos	N/A	Low
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	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
Q4132	Grafix core, grafixpl core	High	High

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	Proposed CY 2023 High/Low Cost Assignment
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	High
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	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 px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	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, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High
Q4158	Kerecis omega3, per sq 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
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	Low	High*
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	High
Q4173	Palingen or palingen xplus	High	High*
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	High	High*
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	High	High
Q4190	Artacent ac 1 sq cm	High	High*
Q4191	Restorigin 1 sq cm	Low	High

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	Proposed CY 2023 High/Low Cost Assignment
Q4193	Coll-e-derm 1 sq cm	High	High
Q4194	Novachor 1 sq cm	High	High
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	High	High
Q4199	Cygnus matrix, per sq cm	N/A	High
Q4200	Skin te 1 sq cm	High	High
Q4201	Matrion 1 sq cm	High	High
Q4203	Derma-gide, 1 sq cm	High	High
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High*
Q4209	Surgraft per sq cm	High	High*
Q4210	Axolotl graf dualgraf sq cm	Low	High
Q4211	Amnion bio or axobio sq cm	High	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	High	High*
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhf10-p per sq cm	N/A	Low
Q4225	Amniobind, per sq cm	N/A	Low
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	High	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	Low	Low
Q4232	Corplex, per sq cm	High	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	Low	High
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	High	High
Q4238	Derm-maxx, per sq cm	High	High
Q4239	Amnio-maxx or lite per sq cm	High	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	Low
Q4249	Amniply, per sq cm	Low	High
Q4250	AmnioAMP-MP per sq cm	Low	Low
Q4254	Novafix dl per sq cm	Low	High
Q4255	Reguard, topical use per sq	Low	Low
Q4256	Mlg complet, per sq cm	Low	Low

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	Proposed CY 2023 High/Low Cost Assignment
Q4257	Relese, per sq cm	Low	Low
Q4258	Enverse, per sq cm	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2023, but are assigned to the high cost group because they were assigned to the high cost group in CY 2022.

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c. Proposed Retirement of HCPCS Code C1849 (Skin Substitute, Synthetic, Resorbable, by per Square Centimeter)

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86064 to 86067), we revised our description of skin substitutes to include synthetic products, in addition to biological products. We also established HCPCS code C1849 to facilitate payment for synthetic graft skin substitute products in the outpatient hospital setting. HCPCS code C1849 was established in response to the need to pay for graft skin substitute application services performed with synthetic graft skin substitute products in the OPPS in a manner comparable to how we pay for graft skin substitute application services performed with biological graft skin substitute products, and was designed to describe any synthetic graft skin substitute product. We did not anticipate creating product specific HCPCS codes for synthetic graft skin substitute products.

We assigned HCPCS code C1849 to the high cost skin substitute group based on our alternative methodology to assign products with WAC or AWP pricing that exceeds the MUC threshold to the high cost skin substitute group (85 FR 86066). When the CY 2021 OPPS/ASC final rule with comment period was issued, we were aware of one synthetic graft skin substitute product described by HCPCS code C1849. The manufacturer provided WAC pricing data that showed the cost of the product was above the MUC threshold for graft skin substitute products and therefore we determined that HCPCS code C1849 should be assigned to the high cost skin substitute group. We noted that, as more synthetic graft skin substitute products are identified as being described by HCPCS code C1849, we would use their pricing data to calculate an average price for the products described by HCPCS code C1849 to determine whether HCPCS code C1849 should be assigned to the high cost or low cost skin substitute group. In the CY 2022 OPPS/ASC final rule with comment period, we stated that we had identified multiple synthetic skin substitute products that could be described by HCPCS code C1849. The average of the WAC pricing data for these products exceeded the MUC threshold (86 FR 63563). Therefore, we assigned HCPCS code C1849 to the high cost skin substitute group in CY 2022 (86 FR 63652).

While we created a single synthetic skin substitute HCPCS code for use under the OPPS beginning in CY 2021, for the physician office setting we established product-specific HCPCS codes for several graft skin substitute products that were described as synthetic skin substitute products in CY 2022 (86 FR 65119 through 65123). Because we anticipated that any graft skin substitute product assigned to the HCPCS A2XXX code series would be a synthetic product that also would be described by HCPCS code C1849 under the OPPS, we decided that graft skin substitute products assigned to the HCPCS A2XXX series would not be payable under the OPPS. Although we would pay for these products when identified by codes in the HCPCS A2XXX series in the physician office setting, it was not necessary to also make these codes payable under the OPPS because we had established HCPCS code C1849 to report the use of synthetic graft skin substitute products with graft skin substitute procedures for payment under the OPPS.

Starting in January 2022, however, all new skin substitute products with an FDA 510(k) clearance received product-specific A-codes in the HCPCS A2XXX series. FDA 510(k)-cleared skin substitute products include both biological products that are not human cell, tissue, or cellular or tissue-based products (HCT/Ps) as well as synthetic products. The use of product-specific A-codes to identify all FDA 510(k) skin substitute products meant that several of the graft skin substitute products assigned product-specific codes in the A2XXX series starting January 1, 2022 were biological graft skin substitutes with an FDA 510(k) clearance. While graft synthetic skin substitute products are described by HCPCS code C1849, FDA 510(k)-cleared biological products are not. However, for OPPS purposes, all graft skin substitute products with product-specific A-codes were assigned status indicator A under the OPPS (Not paid under the OPPS. Paid by [Medicare Administrative Contractors] under a fee schedule or payment system other than the OPPS). Previously, biological skin substitute products with an FDA 510(k) clearance were assigned product-specific Q-codes, which are bundled into payment with the associated procedure under the OPPS. However, starting in January 2022, skin substitute products with a FDA 510(k) clearance were no longer being assigned product-specific Q-codes.

Because some of the codes in the HCPCS A2XXX series identify biological skin substitute products that need to be payable under the OPPS, and because we cannot make only certain codes in the HCPCS A-code series payable and not others, we made the HCPCS A2XXX series payable under the OPPS earlier this year. Effective April 1, 2022, in the ''April 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS)—Change Request 12666'' (*https://www.cms.gov/files/document/r11305cp.pdf*), we changed the status indicator of all skin substitute products described in the HCPCS A2XXX series, including synthetic graft skin substitutes, to ''N'' (Paid under OPPS; payment is packaged into payment for other services). This change allowed packaged payment under the OPPS to be made for these products when furnished with skin substitute application procedures in the hospital outpatient department setting. We also assigned unclassified skin substitute products described by HCPCS code A4100 (Skin substitute, FDA cleared as a device, not otherwise specified) status indicator ''N'' in this Change Request and provided that payment for products identified with this code is packaged under the OPPS. HCPCS code A4100 is used to describe skin substitute products with FDA 510(k) clearance that

do not have a product-specific HCPCS code, which includes unclassified synthetic graft skin substitutes. Graft skin substitute products with product-specific codes in the HCPCS A2XXX series or that are described by HCPCS code A4100 are subject to the same policies as other graft skin substitute products as described by section V.B.7.b of the CY 2022 OPPS/ASC final rule with comment (86 FR 63650 through 63658).

Because we now make payment under the OPPS for product-specific HCPCS A-codes for synthetic graft skin substitute products and for unclassified synthetic graft skin substitute products and other unclassified FDA 510(k)-cleared products identified by HCPCS code A4100, HCPCS code C1849 is no longer necessary to bill for these products when they are used in the hospital outpatient department with graft skin substitute application procedures. In addition to being unnecessary, we are also concerned that the continued existence of HCPCS code C1849 may lead to confusion among providers regarding which HCPCS code to report on a claim if it is not retired, as there are currently two codes that can be reported in the hospital outpatient department setting when a synthetic graft skin substitute product is used: HCPCS code C1849, which can be used for any synthetic skin substitute, or the code in the HCPCS A2XXX series that describes the specific synthetic graft skin substitute product. For these reasons, we believe it is important to retire HCPCS code C1849.

Nonetheless, we do not simply want to retire this code without making accompanying proposals to ensure that synthetic graft skin substitute products that either currently have a product-specific HCPCS code or may receive a product-specific HCPCS code in the future and are currently assigned to the high cost skin substitute group continue to be assigned to the high cost skin substitute group after the retirement of HCPCS code C1849. Most synthetic graft skin substitute products have less than 2 years of claims data and would not have cost data for us to review to determine if the products could be assigned to the high cost group. If the product manufacturers do not send WAC pricing data to us, the products would have to be assigned to the low cost group because of a lack of cost information. Submitting WAC pricing to have a skin substitute assigned to the high cost group is voluntary for manufacturers. Establishing a policy to continue to assign synthetic graft skin substitute products that are currently described by HCPCS code C1849 or would be described by HCPCS code C1849 to the high cost skin substitute group would allow manufacturers and providers to better forecast payment for synthetic graft skin substitute products, and protect them from unanticipated payment reductions. This proposal is consistent with our proposed policy in section V.B.7.b in this proposed rule that any skin substitute product that was assigned to the high cost group in CY 2022 would be continue to be assigned to the high cost group for CY 2023, regardless of whether it exceeds or falls below the CY 2023 MUC or PDC threshold, which has been our standard practice since CY 2018. Both of these proposals promote price stability for both manufacturers and providers and eliminate the risk that a skin substitute product that is currently assigned to the high cost skin substitute group would be reassigned to the low cost skin substitute group.

In summary, for CY 2023, we propose to delete HCPCS code C1849 (Skin substitute, synthetic, resorbable, by per square centimeter). We also propose that any graft skin substitute product that is currently assigned a product-specific code in the HCPCS A2XXX series and is appropriately described by HCPCS code C1849 or is assigned a product-specific code in the HCPCS A2XXX series in the future and is appropriately described by HCPCS code C1849 be assigned to the high cost skin substitute group. We want to ensure synthetic graft skin substitute products continue to remain in the high cost skin substitute group throughout CY 2023 and do not risk reassignment to the low cost group during the transition from using HCPCS code C1849 to a product-specific A-codes even if cost and pricing data are not available for these products. We believe this policy would promote payment stability for providers and other stakeholders when using synthetic graft skin substitute products consistent with our long-standing policy that keeps graft skin substitute products in the high cost group for subsequent years once a product is assigned to the high cost group for a given year.

We also propose that HCPCS code A4100 (Skin substitute, fda cleared as a device, not otherwise specified) be assigned to the low cost skin substitute group, which is consistent with our existing payment policy that unclassified graft skin substitute products be assigned to the low cost skin substitute group. We look forward to comments on these proposals.

d. Key Objectives/Roadmap for Consistent Treatment of Skin Substitutes

We believe outlining our HCPCS Level II coding and payment policy objectives in this proposed rule will be beneficial for interested parties, as we work to create a consistent approach for treatment of the suite of products we have referred to as skin substitutes. We have a number of objectives related to refining Medicare policies in this area, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting; (2) ensuring that all skin substitute products are assigned an appropriate HCPCS code; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal based material, so we can incorporate payment methodologies that are more consistent; and (4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. Interested parties have asked CMS to address what they have described as inconsistencies in our payment and coding policies, indicating that treating clinically similar products (for example, animal-based and synthetic skin products) differently for purposes of payment is confusing and problematic for healthcare providers and patients. These concerns exist specifically within the physician office setting; however, interested parties have also indicated that further alignment of our policies across the physician office and hospital outpatient department settings would reduce confusion.

Interested parties have suggested that all skin substitutes, regardless of the inclusion of human, animal, or synthetic material in the product, should be treated as drugs and biological products. Furthermore, they believe all skin substitute products should receive product-specific ''Q'' codes and receive separate payment under the ASP+6 methodology. They have expressed confusion regarding our assignment of HCPCS Level II ''A'' codes to the 10 skin substitute products in accordance with the policy finalized in the CY 2022 PFS final rule, which we typically assign to identify ambulance services and medical supplies, instead of ''Q'' codes, which we typically assign to identify drugs, biologicals, and medical equipment or services not identified by national HCPCS Level II codes. They have indicated that the use of ''A'' HCPCS codes has caused confusion, not only for interested parties, but also for the A/B MACs, who

the interested parties assert, have inconsistently processed submitted claims, in part because they are assigned HCPCS ''A'' codes that are treated as supplies, which are subject to contractor pricing under the PFS. Additionally, interested parties have expressed concern that physicians and other practitioners are hesitant to use the products associated with ''A'' codes because they are unsure if they will be paid appropriately for using those products. When considering potential changes to policies involving skin substitutes, we believe it would be appropriate to take a phased approach over the next 1 to 5 years, that allows CMS sufficient time to consider input from interested parties on coding and policy changes primarily through our rulemaking process, and to account for FDA's regulation of these products, with the goal of avoiding unintended impacts on access to medically necessary care involving the use of these products.

We welcome comment on our policy objectives for creating a consistent approach for treatment of the suite of products we have referred to as skin substitutes. Additionally, we welcome feedback on our phased approach and associated timeline. To achieve our objective of creating a consistent approach for paying for skin substitutes across the physician office and hospital outpatient department setting, we are including similar proposed changes in the CY 2023 PFS proposed rule, which will be issued near the time this proposed rule is issued.

e. Changing the Terminology of Skin Substitutes

As we work to clarify our policies for these products, we believe that the existing terminology of ''skin substitutes'' is problematic as it is an overly broad misnomer. In the CY 2021 OPPS/ASC final rule with comment period, we revised our description of skin substitutes to refer to a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers (85 FR 80605). We noted that skin substitute products are not a substitute for a skin graft as they do not actually function like human skin that is grafted onto a wound. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue. We also clarified that our definition of skin substitutes does not include bandages or standard dressings, and that within the hospital outpatient department, these items cannot be assigned to either the high cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278. (85 FR 86066).

While this definition has been updated to provide clarity in that synthetic products are considered to be skin substitutes, there is still confusion with the usage of the term skin substitutes because, as noted above in the definition, these skin substitute products are technically not a substitute for skin, but rather, a wound covering that is used to promote healing. We have used the term ''skin substitutes'' to describe the suite of products that are currently referred to as skin substitutes. Additionally, the term ''skin substitutes'' is used within the Current Procedural Terminology (CPT®) code series 15271–8 as maintained by American Medical Association. Also, skin substitute products are generally regulated by the FDA as medical devices under section 510(k) of the Federal Food, Drug and Cosmetic (FD&C) Act and implementing regulations per 21 CFR part 807, or as HCT/Ps solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271.

We believe that improving how we reference these products by using a more accurate and meaningful term will help address confusion among interested parties about how we describe these products, and further, how we pay for them. We propose to replace the term ''skin substitutes'' with the term ''wound care management'' or ''wound care management products.'' We believe this new term more accurately describes the suite of products that are currently referred to as skin substitutes while providing enough specificity to not include bandages or standard dressings, which, as noted above, are not considered skin substitutes. We understand that our proposed terms contain ''care management'' which could be construed to implicate the care management series of AMA CPT codes (*e.g.,* 99424–99427, 99437, 99439, 99487, 99489, 99490–99491) that are commonly used by healthcare professionals. We also understand that the use of our proposed terms with ''management'' in our proposed terms might be construed by some to implicate AMA CPT Evaluation or Assessment and Management (E/M) codes. We would like to clarify that the proposed terms ''wound care management'' and ''wound care management products'' would not implicate the care management series of AMA CPT codes (*e.g.,* 99424–99427, 99437, 99439, 99487, 99489, 99490–99491), or our own G-codes that describe care management services. Nor would our proposed terms relate to the AMA CPT E/M codes. Unlike ''care management'' or ''evaluation and management'' codes and services, the proposed terms would describe a category of items or products, not a type of services. Lastly, we also considered alternate terms such as wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds but believe the proposed terms are more technically accurate and descriptive for how these products are used than the alternative's considered.

We solicit feedback on our proposal to change the terminology we use for the suite of products referred to as ''skin substitutes'' to instead use the term ''wound care management'' or ''wound care management products'' and on the alternative terms we considered, including wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds. We are particularly interested in how these products are referenced in current CPT coding and would appreciate feedback from the CPT Editorial Panel and other interested parties on how to address the challenges we discuss above. We also are interested in feedback on other possible terms that could be used to more meaningfully and accurately describe the suite of products currently referred to as skin substitutes.

8. Radioisotopes Derived From Non-Highly Enriched Uranium (Non-HEU) 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, has been produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States wanted to eliminate domestic reliance on these reactors, and has been 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, but it was expected that this change in the supply source for the radioisotope used for modern medical imaging would introduce new costs into the payment system that were 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 68323).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation was that this additional payment would 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 68321). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipated the conversion of Tc-99m production from non-HEU sources would be completed at the end of 2019.[124] However, the Secretary of Energy issued a certification effective January 2, 2020, stating that there continued to be an insufficient global supply of molybdenum-99 (Mo-99), which is the source of Tc-99m, produced without the use of HEU available to satisfy the domestic U.S. market (85 FR 3362). The January 2, 2020, certification was to remain in effect for up to two years.

The Secretary of Energy issued a new certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). This certification stated that there is a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. The Department of Energy also expects that the last HEU reactor that produces Mo-99 for medical providers in the United States will finish its conversion to a non-HEU reactor by December 31, 2022. In CY 2019, we stated that we would reassess the non-HEU incentive payment policy once conversion to non-HEU sources is closer to completion or has been completed (83 FR 58979). There is now a sufficient supply of non-HEU-sourced Mo-99 in the United States, and by CY 2023, there will be no available supply of HEU-sourced Mo-99 in the United States. Therefore, we believe that the conversion to non-HEU sources of Tc-99m has reached a point where a reassessment of the policy is necessary.

In the OPPS, diagnostic radiopharmaceuticals are packaged into the cost of the associated diagnostic imaging procedure no matter the per day cost amount of the radiopharmaceutical. The cost of the radiopharmaceutical is included as a part of the cost of the diagnostic imaging procedure and is reported through Medicare claims data. Medicare claims data used to set payment rates under the OPPS generally is from two years prior to the payment year.

That means that the likely claims data used to set payment rates for CY 2023 (CY 2021 claims data) and CY 2024 (CY 2022 claims data) would likely contain claims for diagnostic radiopharmaceuticals that would reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc-99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. The cost of HEU-sourced Tc-99m is substantially lower than the cost of non-HEU-sourced Tc-99m. Therefore, providers using radiopharmaceuticals that only contain non-HEU-sourced Tc-99m might not receive a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. We believe that extending the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would help to prevent any underpayment for non-HEU-sourced Tc-99m. Starting in CY 2025, the Medicare claims data utilized to set payment rates (likely CY 2023 claims data) will only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, which means the data will reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that will be used by providers in CY 2025. As a result, there will no longer be a need for the additional $10 add-on payment for CY 2025 or future years.

For CY 2023 and CY 2024, we propose to continue the additional $10 payment to ensure providers receive sufficient payment for diagnostic radiopharmaceuticals containing Tc-99m until such time as the full cost of non-HEU-sourced Tc-99m is reflected in the Medicare claims data. We also propose that the additional $10 payment will end after December 31, 2024, since beginning with CY 2025, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m. We look forward to comments on our proposals.

C. Proposal in Physician Fee Schedule Proposed Rule To Require HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (''the Infrastructure Act'') amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. Section III.A. of the CY 2023 PFS proposed rule includes proposals to implement section 90004 of the Infrastructure Act, including a proposal that hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPPS or ASC payment system. Specifically, we propose in the CY 2023 PFS proposed rule that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug, if any, that were discarded for dates of service during a relevant quarter for the purpose of calculating the refund amount described in section 1847A(h)(3) of the Act. The CY 2023 PFS proposed rule also proposes to require HOPDs and ASCs to use a separate modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

Because the CY 2023 PFS proposed rule proposes to codify certain billing requirements for HOPDs and ASCs, we want to ensure interested parties are aware of them and know to refer to that rule for a full description of the proposed policy. Interested parties should submit comments on this and any other proposals to implement Section 90004 of the Infrastructure Act in response to the CY 2023 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2023 PFS final rule. We note that this same notice appears in section XIII.D.3 of this proposed rule.

[124] National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23563*.

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata 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 2023 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 2023. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2022 or beginning in CY 2023. The sum of the proposed CY 2023 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2023 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2023, we also propose 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. Our estimate of drug and biological pass-through payment for CY 2023 for this group of items is $622.6 million, as discussed below, because we propose that most non pass-through separately payable drugs and biologicals would be paid under the CY 2023 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which we formally propose would be paid at ASP minus 22.5 percent, and because we propose to pay for CY 2023 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A of this proposed rule. However, in light of the Supreme Court's recent decision, we fully anticipate applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule for CY 2023, in which case our estimate of drug and biological pass-through payment for CY 2023 for this group of items is $29.9 million.

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 are not separately paid. In addition, we policy-package all non pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c of this proposed rule. We propose that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2023, less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2023 is not $0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In section V.A.6 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 propose 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 propose to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-

through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2023. 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 2022 or beginning in CY 2023. The sum of the CY 2023 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2023 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2023

For CY 2023, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2023, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2022 (86 FR 63659). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2023, there are 14 active categories for CY 2023. The active categories are described by HCPCS codes C1052, C1062, C1734, C1748, C1761, C1823, C1824, C1825, C1831, C1832, C1833, C1839, C1982 and C2596. Based on the information from the device manufacturers, we estimate that HCPCS code C1052 will cost $162,000 in pass-through expenditures in CY 2023, HCPCS C1062 will cost $1.9 million in pass-through expenditures in CY 2023, HCPCS code C1734 will cost $2.2 million in pass-through expenditures in CY 2023, HCPCS code C1748 will cost $2.2 million in pass-through expenditures in CY 2023, HCPCS code C1761 will cost $9.9 million in pass-through expenditures in CY 2023, HCPCS code C1823 will cost $1.5 million in pass-through expenditures in CY 2023, HCPCS code C1824 will cost $1.5 million pass-through expenditures in CY 2023, HCPCS code C1825 will cost $749,000 in pass-through expenditures in CY 2023, HCPCS code C1831 will cost $29,900 in pass-through expenditures in CY 2023, HCPCS code C1832 will cost $18.4 million in pass-through expenditures in CY 2023, HCPCS code C1833 will cost $5.1 million in pass-through expenditures in CY 2023, HCPCS code C1839 will cost $138,000 in pass-through expenditures in CY 2023, HCPCS code C1982 will cost $1.2 million in pass-through expenditures in CY 2023, HCPCS code C2596 will cost $2.8 million in pass-through expenditures in CY 2023. Therefore, we propose an estimate for the first group of devices of $48 million.

In estimating our proposed CY 2023 pass-through spending for device categories in the second group, we included: device categories that we assumed at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2023; additional device categories that we estimated could be approved for pass-through status after the development of this proposed rule and before January 1, 2023; and contingent projections for new device categories established in the second through fourth quarters of CY 2023. For CY 2023, we propose 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 2023 pass-through spending for this second group of device categories is $101.4 million.

To estimate proposed CY 2023 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 at least one quarter in CY 2023, we propose to use the CY 2021 Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2023 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 2023, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, which we formally propose to pay at ASP minus 22.5 percent. Therefore, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount is $592.7 million for this group of drugs. However, in light of the Supreme Court's recent decision, we fully anticipate applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule for CY 2023, in which case, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount is $0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we propose to include in the CY 2023 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, which we estimate for CY 2023 for the first group of policy-packaged drugs to be $19.9 million.

To estimate proposed CY 2023 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 or recently became eligible for pass-through payment in CY 2023, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2023, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2023), we propose 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 2023 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2023 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 $10 million.

We estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2023 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2023 would be approximately $772.0 million (approximately $149.4 million for device categories and approximately $622.6 million for drugs and biologicals) which represents 0.90 percent of total projected OPPS payments for CY 2023 (approximately $86.2 billion). In light of the Supreme Court's recent decision, we fully anticipate applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule for CY 2023, in light of the Supreme Court's recent decision, in which case we would estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2023 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2023 would be approximately $179.3 million (approximately $149.4 million for device categories and approximately $29.9 million for drugs and biologicals). This alternative would represent only 0.21 percent of total projected OPPS payments for CY 2023. Therefore, we estimate that pass-through spending in CY 2023 will not amount to 2.0 percent of total projected OPPS CY 2023 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2023, we propose to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2023. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of this payment policy, 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 continue to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the clinic visit payment policy applies for CY 2023 and subsequent years. More specifically, we are continuing to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus provider-based departments. The PFS-equivalent rate for CY 2023 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate). Under this policy, these departments will be paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2023) for the clinic visit service in CY 2023. Additionally, for CY 2023 we propose that excepted off-campus provider-based departments (PBDs) (departments that bill the modifier ''PO'' on claim lines) of rural Sole Community Hospitals, as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, would be exempt from the clinic visit payment policy that applies a Physician Fee Schedule-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this proposal we refer readers to section X of this proposed rule. We will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

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. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, 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 (76 FR 74348 through

74352). 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. 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) and 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 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 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In 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 and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, 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).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued 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, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID–19 PHE.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. Since the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666), we explained that we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would have ordinarily used for CY 2022 ratesetting, and this included changes in the claims for partial hospitalization. We explained that significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data were not the best overall approximation of expected PHP services in CY 2022. Therefore, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

B. Proposed PHP APC Update for CY 2023

1. Proposed PHP APC Geometric Mean Per Diem Costs

For CY 2023 only, we propose to calculate the CMHC and hospital-based PHP geometric mean per diem costs in accordance with our existing methodology, except that while we propose to use the latest available CY 2021 claims data, we propose to continue to use the cost data that was available for the CY 2021 rulemaking, which is the same cost data used for the CY 2022 rulemaking (86 FR 63665 through 63666). This proposal is consistent with the overall proposed use of cost data for the OPPS, which is discussed in section X.D of this proposed rule. Following this proposed methodology, we propose to use the geometric mean per diem cost of $131.71 for CMHCs as the basis for developing the CY 2023 CMHC APC per diem rate, and to use the geometric mean per diem cost of $264.06 as the basis for developing the CY 2023 hospital-based APC per diem rate. In addition, as discussed in the following sections, we propose not to include data from certain nonstandard cost center lines in the OPPS ratesetting database construction for CY 2023; however, we are requesting information from the public about these data for use in future ratesetting. Lastly, in accordance with our longstanding policy, we propose to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)). These proposals are discussed in more detail in the following sections.

2. Development of the PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2023, we followed 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 calculate the PHP

APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687) and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666). As discussed in section VIII.B.1 of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing three or more services. Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing three or more services. As discussed in section VIII.B.1.a of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666 through 63668), the costs for CMHC service days are calculated using cost report information from HCRIS.

As mentioned earlier in this section of this proposed rule, we propose a change from our longstanding practice similar to what we finalized last year in light of the effects of the COVID–19 PHE. We discuss this proposal and our rationale in greater detail in the following paragraphs.

First, we considered whether the latest available CY 2021 claims would be appropriate to use for CY 2023 ratesetting. Ordinarily, the best available claims data is the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2023 OPPS/ASC proposed rule ratesetting, the best available claims data would typically be the 2021 calendar year outpatient claims data processed through December 31, 2021. As discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666), we noted significant decreases in the number of PHP days for both hospital-based PHPs and CMHCs. For this proposed rule, we continue to observe a decrease in the number of hospital-based PHP days in our trimmed CY 2021 claims dataset, which has approximately 18 percent fewer days than the CY 2020 dataset. Likewise, for CMHCs, we continue to observe this decrease in our trimmed CY 2021 claims dataset, which has approximately 32 percent fewer CMHC PHP days than the CY 2020 dataset did. Given the continued effects of COVID–19 observed on the Medicare claims and cost report data, coupled with the expectation for future variants, we believe that it is reasonable to assume that there will continue to be some limited influence of COVID–19 PHE effects on the data we use for ratesetting.

Despite the continued effects of COVID–19 that we note in the PHP data, we also note that even though hospital operations do not appear to have returned to the same levels as 2019, the Medicare outpatient service volumes appear to be returning to more normal pre-pandemic levels. As discussed in section X.D of this proposed rule, based on our review of the CY 2021 outpatient claims available for ratesetting, we observed that the non-PHP outpatient service volumes are generally about halfway between those in the CY 2019 (pre-PHE) claims and CY 2020 (beginning of the PHE) claims, however, we recognize that future COVID–19 variants may have potentially varying effects and we believe it is reasonable to assume that there will continue to be some effects of COVID–19 PHE on the outpatient claims that we use for ratesetting. As a result, we believe that the more recently available CY 2021 claims data would better represent the volume and mix of claims for the CY 2023 OPPS. Accordingly, we believe it is appropriate to use CY 2021 data for purposes of CY 2023 OPPS ratesetting. Consistent with the proposal discussed in section X.D of this proposed rule, we propose to use the latest available CY 2021 claims for CY 2023 PHP ratesetting.

Next, we reviewed the cost report data from the December 2021 HCRIS data set, which we would ordinarily have used for this CY 2023 OPPS/ASC proposed ratesetting. As discussed in greater detail in section X.D of this proposed rule, we believe cost report data that overlap with CY 2020 are too influenced by the COVID–19 PHE for purposes of calculating the CY 2023 PHP payment rates. In the case of PHP, we observed a negative impact of the cost report data from the December 2021 HCRIS data set on the calculated geometric mean per diem cost for CMHCs. Specifically, we observed that the CMHC geometric mean per diem costs calculated using the latest available cost report data from the December 2021 HCRIS data set would be $127.38, which would be a decrease from the cost floor of $136.14 used to calculate the CY 2022 CMHC APC 5853 payment rate (86 FR 63668). Therefore, we believe that it is appropriate to continue to use the same set of cost reports that we used in developing the CY 2021 OPPS, to mitigate the impact of that 2020-based data. We note that we will continue to review the updated cost report data as they are available.

Based on the results of this analysis, we propose to use the cost information from prior to the COVID–19 PHE—in other words, cost information that was available for the CY 2021 OPPS/ASC rulemaking, which is the same as that used last year for the CY 2022 OPPS/ASC rulemaking (86 FR 63665 through 63669). We would specifically use cost report data from the June 2020 HCRIS data set, which only includes cost report data through CY 2019.

Therefore, consistent with what we propose to do for other APCs under the OPPS as discussed in section X.D of this proposed rule, we propose to use the latest available CY 2021 claims, but use the cost information from prior to the COVID–19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs.

Additionally, as mentioned above and discussed in greater detail in section II.A.1.c of this proposed rule, we have identified that we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We have found that hospitals are routinely reporting a number of nonstandard cost centers in this way. One such cost center is cost center 03550, which is used to report Psychiatric/Psychological Services.[125] Based on the program logic to process HCRIS data used for OPPS ratesetting, we obtain the cost center number based on the line and subscript number on which the cost center is reported. Our internal analysis of hospital cost report information found that providers are routinely reporting this cost center on cost report lines other than 35.50 (that is, line 35 subscript 50), and therefore, this nonstandard cost center and others reported this way have not been included in the OPPS ratesetting database construction. Our internal analysis shows that including this additional data could potentially decrease the geometric mean cost of APC 5863 (Partial Hospitalizations (3 or more services) for hospital-based PHPs) by 12 percent.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not

[125] Chapter 40 of the Provider Reimbursement Manual (PRM), Part 2, available on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Paper-Based-Manuals.*

correspond to the cost center number. Additionally, we are concerned about the significant changes in APC geometric mean costs that our analysis indicates would occur if we were to include such lines. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. Therefore, consistent with the proposal at II.A.1.c of this proposed rule for other OPPS services, we propose to not include data from nonstandard cost centers reported on lines that do not correspond to the cost center number in our PHP ratesetting for CY 2023. We are soliciting comment on whether there exist any specific concerns with regards to the accuracy of the data from these nonstandard cost center lines that we would need to consider before including them in future OPPS ratesetting.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this proposed rule, we used HCRIS as the source for the CMHC cost information as discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666) and prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465). However, as discussed above, we propose to use CY 2021 claims data and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2023 CMHC PHP APC per diem cost.

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 were applied, there were 27 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2023 ratesetting, one CMHC had a geometric mean cost per day above the trim's upper limit of $466.01, and one CMHC had a geometric mean cost per day below the trim's lower limit of $37.29. Therefore, we are excluding data for ratesetting from these two CMHCs.

In accordance with our PHP ratesetting methodology (80 FR 70465), we also remove 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). For this CY 2023 proposed rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. We also exclude providers without any days containing 3 or more units of PHP-allowable services. One provider is excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. In addition to our trims and data exclusions, before calculating 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 that is not available or any CMHC CCR greater than one to the statewide hospital CCR associated with the provider's urban/rural designation and their State location (80 FR 70463). For this proposed rule ratesetting, there was one CMHC with a CCR greater than one, and four CMHCs with missing CCR information. Therefore, we are defaulting the CCRs for these five CMHCs for ratesetting to the applicable statewide hospital CCR for each CMHC based on its urban/rural designation and its State location.

In summary, the application of these data preparation steps resulted in an adjusted CCR during our ratesetting process for five CMHCs having either a CCR greater than one or having no CCR. We are also excluding one CMHC because it had no days containing three or more services, and two CMHCs for failing the ±2 standard deviation trim resulting in the inclusion of 24 CMHCs. There were 330 CMHC claims removed during data preparation steps due to the ±2 standard deviation trim or because they either had no PHP-allowable codes or had zero payment days, leaving 3,134 CMHC claims in our CY 2023 proposed ratesetting modeling. After applying all of the previously listed trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691), using the CMHC CCRs calculated based on the cost information from HCRIS as discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666), to calculate the CMHC APC geometric mean per diem cost.[126] The calculated CY 2023 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (CMHC APC 5853) is $131.71, an increase from $129.93 calculated last year for CY 2022 ratesetting (86 FR 63667).

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. However, as discussed above, we propose to use CY 2021 claims data and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2023 hospital-based PHP APC per diem cost. The CY 2021 PHP claims included data for 334 hospital-based PHP providers for our calculations in this CY 2023 OPPS/ASC proposed rule.

Consistent with our policies, as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim. For this proposed rule ratesetting, no hospital-based PHP providers had a CCR greater than 5. Therefore, no hospital-based provider was excluded as

[126] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR (or statewide CCR, where the overall CCR was greater than 1 or was missing) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have three or more services provided to be assigned to CMHC APC 5853. The final geometric mean per diem cost for CMHC APC 5853 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. CMHC service days with costs ±3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the final geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where three or more services were provided.

a result of this trim. In addition, six hospital-based PHPs were removed for having no days with PHP payment. One hospital-based PHP was removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).[127]

Overall, we removed eight hospital-based PHP providers (6 with no PHP payment) + (1 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ±3 SD limits)], resulting in 326 (334 total − 8 excluded) hospital-based PHP providers in the data used for calculating ratesetting.

After completing these data preparation steps, we calculated the CY 2023 geometric mean per diem cost for hospital-based PHP APC 5863 by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 and 79691).[128] The calculated CY 2023 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is $264.06, which is an increase from $253.02 calculated last year for CY 2022 ratesetting (86 FR 63668).

The proposed CY 2023 PHP geometric mean per diem costs are shown in Table 45 and are used to derive the proposed CY 2023 PHP APC per diem rates for CMHCs and hospital-based PHPs. The proposed CY 2023 PHP APC per diem rates are included in Addendum A to this proposed rule (which is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).

TABLE 45: Proposed CY 2023 PHP APC Geometric Mean Per Diem Costs

CY 2023 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	$131.71
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$264.06

C. Outpatient Non-PHP Mental Health Services Furnished Remotely to Partial Hospitalization Patients After the COVID–19 PHE

1. Background

As discussed in the April 30, 2020 interim final rule with comment entitled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 PHE, hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation and provider-based rules to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID–19 PHE. In that same interim final rule (85 FR 27564), we also stated that although these services can be furnished remotely, all other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP still require an order by a physician, must be supervised by a physician, must be certified by a physician, and must be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice. We also stated that in accordance with the longstanding requirements that are detailed in the Medicare Benefit Policy Manual, Pub 100–02, chapter 6, section 70.3, documentation in the medical record of the reason for the visit and the substance of the visit is required.

We received four comments in response to the April 30, 2020 interim final rule with comment regarding the interim final policy for PHP. One commenter, a national nonprofit organization, expressed support for this flexibility to ensure services are available safely to people with Medicare. Another commenter, a healthcare services company, encouraged CMS to ensure that temporary expansion location policies do not abruptly end at the end of the PHE, and supported a flexible transition policy to better ensure continuity of care as hospitals and communities continue

[127] Click on the link labeled ''CY 2023 OPPS/ASC Notice of Proposed Rulemaking'', which can be found under the heading ''Hospital Outpatient Prospective Payment System Rulemaking'' and open the claims accounting document link at the bottom of the page, which is labeled ''2023 NPRM OPPS Claims Accounting (PDF)''.

[128] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have three or more services provided to be assigned to hospital-based PHP APC 5863. The final geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. Hospital-based PHP service days with costs ±3 standard deviations from the geometric mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the final geometric mean per diem cost for hospital-based PHP APC 5863.

to fight the spread of COVID–19 and recover from the impacts of the virus. One national insurance company voiced support for the flexibilities and noted that a major beneficial component of PHP is the structured patient engagement, which can be achieved in the absence of face-to-face interactions. This commenter stated that they believe these flexibilities are necessary to ensure that PHP beneficiaries continue to have access to the level of care they require. They further noted that for PHP patients, requiring face-to-face only interactions would place both beneficiaries and providers at risk of contracting or spreading the coronavirus, but forgoing care could put beneficiaries at risk for relapse and overdose. This commenter also expressed concern about clerical staff lacking the qualifications to provide the services described, and request further language to clarify the scope of this allowance. Another national insurance company expressed support for the use of live-two-way video interactions via remote technology for the PHP level of care when the same level of care and clinical value as an in-person interaction can be achieved during the PHE. However, this commenter expressed concern about the use of only audio communication to provide PHP services. The commenter explained that audio-only delivery of services does not allow for therapeutic groups and ongoing assessments therefore impeding the ability to achieve the clinical benefits of the programs, and cautioned that if PHP services are delivered ineffectively via audio-only communication, the patient risks relapse and inpatient readmission. We noted in the interim final rule that due to the intensive nature of PHP we expected PHP services to be furnished using telecommunications technology involving both audio and video. However, we recognized that in some cases beneficiaries might not have access to video communication technology. In order to maintain beneficiary access to PHP services, only in the case that both audio and video are not possible could the service be furnished exclusively with audio (85 FR 27564).

In the CY 2022 OPPS/ASC proposed rule (86 FR 42187), CMS solicited comments on whether there were changes commenters believed we should make to account for shifting patterns of practice that rely on communication technology to provide mental health services to beneficiaries in their homes. We acknowledged that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care through the use of that technology, and that we were interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes.

Although we did not solicit comments on extending the use of remote technology to provide partial hospitalization services to beneficiaries in their homes after the end of the COVID–19 PHE, we received several comments in response to the CY 2022 OPPS/ASC proposed rule expressing support for the flexibilities allowing PHP services to be furnished to beneficiaries in their homes via telecommunication technology during the COVID–19 PHE and encouraging CMS to maintain these flexibilities beyond the PHE or consider making these temporary policies permanent (86 FR 63750). Commenters expressed that these flexibilities, especially those allowing the use of audio-only telecommunication technology, increase access to vital mental health services amidst a persistent shortage of health care professionals and allow much greater and timelier access to mental health services, especially in rural areas and for vulnerable populations, while also helping drive reductions in the rates at which patients missed appointments. Commenters also shared research and analysis supporting the effectiveness of providing PHP services using telecommunication technology. One academic health center discussed outcomes analysis it conducted of its PHP services and noted that its analysis did not show a decrement in clinical care for patients who received only virtual PHP services. A national association of behavioral healthcare systems shared research showing that the main differences between patients who participated in PHPs via telecommunication technology and those who attended in-person was that those who participated via telecommunication technology had greater lengths of stay and were more likely to stay in treatment until completed.[129] In response to these comments and others that we received pertaining to the comment solicitation, we noted that we would consider them for future rulemaking and that CMS would continue to explore how hospital payment for virtual services could support access to care in underserved and/or rural areas.

[129] *https://www.psychiatrist.com/jcp/covid-19/telehealth-treatment-patients-intensive-acute-care-psychiatric-setting-during-covid-19/.*

2. Outpatient Non-PHP Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes After the COVID–19 PHE

As discussed in section X.A.5 of this proposed rule, we propose that payment under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital. While we are not proposing to recognize these proposed OPPS remote services as PHP services. We are clarifying here that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital if that proposal is finalized.

Additionally, we are reminding readers that section 1835(a)(2)(F) of the Act requires that in the absence of partial hospitalization services, the individual would require inpatient psychiatric care; that is, partial hospitalization services are in lieu of inpatient hospitalization. This requirement is codified in the PHP regulations at § 424.24(e)(1)(i), which requires that the PHP patient certification state that the individual would require inpatient psychiatric care if the partial hospitalization services were not provided. Furthermore, in accordance with § 410.43(c)(7), all PHP patients should have the cognitive and emotional ability to participate in the active treatment process and should be able to tolerate the intensity of the partial hospitalization program.

In addition, we reiterate that the physician certification and plan of care requirements at § 424.24(e)(1) and (2) require that each PHP patient must be under an individualized written plan of treatment that is periodically reviewed by a physician in consultation with appropriate staff participating in the program. This plan of treatment must set forth the physician's diagnosis; the type, amount, duration, and frequency of the services; and the treatment goals under the plan. As discussed in the CY 2009 OPPS/ASC final rule (73 FR 68695), and§ 410.43(c), partial hospitalization programs are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in a patient's plan of care. We expect that PHP patients are receiving the amount and type of services identified in the plan of care for generally all weeks under the program

stated in the plan of care rather than in the actual hours of therapeutic services a patient receives.

In accordance with these requirements, if the proposal at Section X.A.5 is finalized, we expect that a physician would update the patient's PHP plan of care to appropriately reflect any change to the type, amount, duration, or frequency of the therapeutic services planned for that patient in circumstances when a PHP patient receives non-PHP remote mental health services from a hospital outpatient department. The medical documentation should continue to support the patient's eligibility for participation in a PHP.

Lastly, we note that section 1866(e)(2) of the Act includes CMHCs as a Medicare provider of services, but only with respect to the furnishing of partial hospitalization services. As noted earlier in this section, we are not proposing to recognize the proposed OPPS remote services as PHP services; therefore, CMHCs are not permitted to bill Medicare for any remote mental health services furnished by clinical staff of the CMHC in an individual's home. However, a PHP patient who typically receives PHP services at a CMHC could receive non-PHP remote mental health services from a hospital outpatient department if the proposal at section X.A.5 is finalized, or from a physician or other type of practitioner who is authorized to furnish and bill for Medicare telehealth services. As discussed in the following section of this proposed rule, we are requesting information on the need for remote mental health services by CMHC patients, as well as potential pathways CMS could consider to address this need within the current statutory framework.

3. Request for Information Regarding Remote PHP Services Furnished by Hospital Outpatient Departments and CMHCs During the COVID–19 PHE

We are interested in better understanding the use of remote mental health services for PHP patients during the COVID–19 PHE and the potential need for such services in the future among PHP patients who receive care from CMHCs and HOPDs. Specifically, we are requesting public comments on the following questions:

- How have CMHCs and HOPDs used the flexibilities allowing the provision of remote PHP services and incorporated remote PHP services into their operations during the COVID–19 PHE?
- What are the needs and circumstances in which remote PHP services have most often been used? What situations and patient populations have these flexibilities best served? How have these needs, circumstances, and patient populations differed between HOPDs and CMHCs?
- What, if any, barriers would there be to access to remote mental health services for PHP patients of a CMHC? What if any possible pathways do commenters believe might exist to minimize these barriers, while taking into consideration section 1861(ff)(3)(A) of the Act?

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. Please identify the question you are responding to, and include as much data as possible that supports your responses. We look forward to receiving feedback on these topics.

D. Outlier Policy for CMHCs

For 2023, we propose to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar-threshold according to previously established policies. These topics are discussed in more detail. We refer readers to section II.G.1 of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, 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. This 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 (82 FR 59381). In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082).

We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. To calculate the CMHC outlier percentage, we follow three steps:

- *Step 1:* We multiply the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments:

$$(0.01 \times \text{Estimated Total OPPS Payments}) = \text{Estimated Total OPPS Outlier Payments.}$$

- *Step 2:* We estimate CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3 of the CY 2022 OPPS/ASC proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.D.3 of this proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.D.5 of this proposed rule, so any provider's costs

that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we sum all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs − Each Provider's Estimated Multiplier Threshold) = A. If A is greater than 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 × Provider's Total Estimated Per Diem Payments), then cap-adjusted B = (0.08 × Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- *Step 3:* We determine the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1: (Estimated CMHC Outlier Payments/Total OPPS Outlier Payments).

We propose to continue to calculate the CMHC outlier percentage according to previously established policies, and we did not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2023. Therefore, based on our CY 2023 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2023, excluding outlier payments. We proposed to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP 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 PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997), CY 2020 OPPS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083). For CY 2023, we propose to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. That is, for CY 2023, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We propose to continue these policies for partial hospitalization services provided through PHPs for CY 2023. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*).

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, 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). 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). This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years. In the CY 2023 OPPS/ASC proposed rule, we do not propose any changes to this policy.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP 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. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also

impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63508). We propose to continue this policy for CY 2023.

IX. Proposed Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the invasive nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, for the reasons described above, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Interested parties are encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

We traditionally have used five longstanding criteria to determine whether a procedure should be removed from the IPO list. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether it should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We have explained that while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed, instead, the case for removal is strengthened with the more criteria the service meets. The criteria for assessing procedures for removal from the IPO list are 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 furnished 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 furnished in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

In the past, we have requested that interested parties submit corresponding evidence in support of their claims that a code or group of codes met the longstanding criteria for removal from the IPO list and was safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our clinicians thoroughly reviewed all information submitted within the context of the established criteria and if, following this review, we determined that there was sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assigned the service to an APC and included it as a payable procedure under the OPPS (67 FR 66740). We determine the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and review the Medicare Severity Diagnosis Related Groups (MS–DRG) rate for the service under the IPPS, though we note we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting.

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide for payment for them under the OPPS (65 FR 18443). Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and, therefore, that will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO

list to determine whether any services should be removed.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088) we finalized a policy to eliminate the IPO list over the course of 3 years (85 FR 86093). We revised our regulation at § 419.22(n) to state that, effective on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in CY 2021.

In the CY 2022 OPPS/ASC final rule with comment period, we halted the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list using the above five criteria, we returned most services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022 (86 FR 63671 through 63736). We also amended the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition. We also finalized our proposal to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23 (86 FR 63678).

B. Proposed Changes to the Inpatient Only (IPO) List

Using the five criteria listed above, for CY 2023, we have identified 10 services described by the following codes that we propose to remove from the IPO list for CY 2023: CPT code 16036 (Escharotomy; each additional incision (list separately in addition to code for primary procedure)); CPT code 22632 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)); CPT code 21141 (Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft); CPT code 21142 (Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft); CPT code 21143 (Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft); CPT code 21194 (Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)); CPT code 21196 (Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation); CPT code 21347 (Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches); CPT code 21366 (Open treatment of complicated (*e.g.*, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)); and CPT code 21422 (Open treatment of palatal or maxillary fracture (lefort i type);). The services that we propose to remove from the IPO list for CY 2023 and subsequent years, including the CPT codes, long descriptors, and the proposed CY 2023 payment indicators and APC assignments are displayed in Table M1 of this proposed rule.

As noted above, we propose to remove the service described by CPT code 16036 from the IPO list for CY 2023. After reviewing the clinical characteristics of the service described by CPT code 16036, we believe that this procedure meets criteria 2 and 3 in our regulation text at § 419.23(b)(2) and (3) because the simplest procedure described by the code may be performed in most outpatient departments and the service or procedure is related to codes that CMS has already removed from the IPO list. CPT code 16036 is an add-on code that is typically billed with the primary procedure described by CPT code 16035 (Escharotomy; initial incision), which was removed from the IPO list in CY 2007 OPPS/ASC final rule with comment period (71 FR 68156). For CY 2023, we propose to assign CPT code 16036 to status indicator ''N''. We are seeking public comment on our conclusion that the service described by CPT code 16036 meets criteria 2 and 3 as well as our proposal to assign this service to status indicator ''N'' for CY 2023.

Additionally, we propose to remove the service described by CPT code 22632 from the IPO list for CY 2023. CPT code 22632 is an add-on code that is typically billed with the primary procedure described by CPT code 22630 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar), which was removed from the IPO list in CY 2021 (86 FR 63708). CPT code 22632 was previously removed from the IPO list in CY 2021 as part of the first stage of the elimination of the IPO list, but was then returned to the list for CY 2022 when the elimination of the IPO list was halted. After further in-depth clinical review of this procedure, we believe CPT code 22632 meets criteria 2 and 3 in our regulation text at § 419.23(b)(2) and (3) because the simplest procedure described by the code may be performed in most outpatient departments and it is related to CPT code 22630, which CMS has already removed from the IPO list. For CY 2023, we propose to assign CPT code 22632 to status indicator ''N''. We are seeking public comment on our conclusion that the service described by CPT code 22632 meets criteria 2 and 3 as well as our proposal to assign this service to status indicator ''N'' for CY 2023.

As stated above, we also propose to remove the following maxillofacial procedures from the IPO list: CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422. These services were previously removed from the IPO list in CY 2021 as part of the first phase of the elimination of the IPO list and were added back to the IPO list when the elimination of the IPO list was halted for CY 2022. After further in-depth review of the clinical characteristics of these procedures, the claims data, and additional evidence provided by interested parties, we believe these services meet criteria 1, 2, and 3 in the regulation text at § 419.23(b)(1), (2), and (3) because most outpatient departments are equipped to provide the procedures; the simplest procedures described by the codes may be performed in most outpatient departments; and the procedures are related to codes that CMS has already removed from the IPO list and we propose to remove them from the IPO list. We propose to assign these eight services to APC 5165—Level 5 ENT Procedures and status indictor ''J1''. We are seeking public comment on our conclusion that the services described by CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422 meet criteria 1, 2, and 3 and our proposal to assign these services to APC 5165—Level 5 ENT Procedures and status indicator ''J1''.

We propose to add eight services that were newly created by the AMA CPT Editorial Panel for CY 2023 to the IPO list. These services, which will be effective on January 1, 2023, are described by CPT codes 157X1, 228XX, 49X06, 49X10, 49X11, 49X12, 49X13, and 49X14. After clinical review of these services, we found that they require a hospital inpatient admission or stay and we propose to assign these services to status indicator ''C'' for CY 2023. The CPT codes, long descriptors, and the proposed CY 2023 payment indicators are displayed in Table 46.

Table 46 below contains the proposed changes to the IPO list for CY 2023. The complete list of codes describing services that are proposed to be designated as inpatient only services beginning in CY 2023 is also included as Addendum E to this proposed rule, which is available via the internet on the CMS website.

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TABLE 46: PROPOSED CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2023

CY 2023 CPT Code	CY 2023 Long Descriptor	Proposed Action	CY 2023 OPPS Proposed Status Indicator	CY 2023 OPPS Proposed APC Assignment
16036	Escharotomy; each additional incision (list separately in addition to code for primary procedure)	Remove from the IPO list	N	N/A
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	Remove from the IPO list	N	N/A
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft	Remove from the IPO list	J1	5165
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	Remove from the IPO list	J1	5165
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	Remove from the IPO list	J1	5165
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	Remove from the IPO list	J1	5165
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	Remove from the IPO list	J1	5165
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	Remove from the IPO list	J1	5165
21366	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar	Remove from the IPO list	J1	5165

CY 2023 CPT Code	CY 2023 Long Descriptor	Proposed Action	CY 2023 OPPS Proposed Status Indicator	CY 2023 OPPS Proposed APC Assignment
	tripod; with bone grafting (includes obtaining graft)			
21422	Open treatment of palatal or maxillary fracture (lefort i type);	Remove from the IPO list	J1	5165
157X1	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma	Add to the IPO list	C	N/A
228XX	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	Add to the IPO list	C	N/A
49X06	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	Add to the IPO list	C	N/A
49X10	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	Add to the IPO list	C	N/A
49X11	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	Add to the IPO list	C	N/A
49X12	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie,	Add to the IPO list	C	N/A

CY 2023 CPT Code	CY 2023 Long Descriptor	Proposed Action	CY 2023 OPPS Proposed Status Indicator	CY 2023 OPPS Proposed APC Assignment
	open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, Cincarcerated or strangulated			
49X13	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible	Add to the IPO list	C	N/A
49X14	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated	Add to the IPO list	C	N/A

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X. Nonrecurring Policy Changes

A. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

1. Payment for Mental Health Services Furnished as Medicare Telehealth Services or by Rural Health Clinics and Federally Qualified Health Centers

Under the Physician Fee Schedule (PFS), Medicare makes payment to professionals and other suppliers for physicians' services, including certain diagnostic tests and preventive services. Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of Medicare telehealth services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunications technology. Section 1834(m)(4)(D) and (E) of the Act specify the types of health care professionals that can furnish and be paid for Medicare telehealth services (referred to as distant site physicians and practitioners). Section 1834(m)(4)(C) also generally limits the types of settings and geographic locations where a beneficiary can receive telehealth services (referred to as originating sites) to medical care settings in rural areas.

Due to the circumstances of the COVID–19 pandemic, particularly the need to maintain physical distance to avoid exposure to the virus, we anticipated that health care practitioners would develop new approaches to providing care using various forms of technology when they are not physically present with the patient. We established several flexibilities to accommodate these changes in the delivery of care. For Medicare telehealth services, using waiver authority under section 1135(b)(8) of the Act in response to the PHE for the COVID–19 pandemic, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE. We also used waiver authority to allow certain telehealth services to be furnished via audio-only telecommunications technology during the PHE.

Division CC, section 123 of the Consolidated Appropriations Act, 2021 (CAA, 2021), modified the circumstances under which payment is made under the PFS for mental health services furnished via telehealth technology following the PHE. Specifically, section 123 removed the geographic originating site restrictions and added the home of the individual as a permissible originating site for Medicare telehealth services when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. These amendments were implemented in the CY 2022 PFS final rule (86 FR 65055 through 65059). In the CY 2022 PFS final rule we also implemented a similar policy for mental health visits furnished by staff of RHCs and FQHCs (86 FR 65207 through 65211).

2. Hospital Payment for Mental Health Services Furnished Remotely During the PHE for COVID–19

For services that are not paid under the PFS, there is no statutory provision similar to section 1834(m) that addresses payment for services furnished by hospitals or other institutional providers to beneficiaries who are not physically located in the hospital or facility. CMS does pay, however, for certain covered OPD services that do not require the beneficiary's physical presence in the hospital. In CY 2015, CMS began paying for CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic

conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored), which describes non-face-to-face care management services furnished by clinical staff under the direction of a physician or other qualified health professional over the course of a calendar month to a beneficiary who is not physically in the hospital (see Addendum B at: *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1613-FC*). In CY 2019, the OPPS began making payment for certain remote monitoring services, which similarly involve a beneficiary who is not physically in the hospital but who is using a monitoring device that transmits data to hospital staff (see Addendum B at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC*).

In many cases, hospitals provide hospital outpatient mental and behavioral health services (collectively hereafter, mental health services) that are furnished by hospital-employed counselors or other licensed professionals. Examples of these services include psychoanalysis, psychotherapy, and other counseling services. For some of these types of professionals (for example, certain mental health counselors such as marriage and family therapists or licensed professional counselors), the Medicare statute does not have a benefit category that would allow them to bill independently for their services. These services can, in many cases, be covered when furnished by providers such as hospitals and paid under the OPPS.

As we explained in the interim final rule with comment period published on May 8, 2020, in the **Federal Register** titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (the May 8th COVID–19 IFC) (85 FR 27550, 27563), outpatient mental health services, education, and training services require communication and interaction between the patient and the clinical staff providing the service. We stated that facility staff can effectively furnish these services using telecommunications technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them. We further explained that blanket waivers in effect during the COVID–19 PHE allow the hospital to consider the beneficiary's home, and any other temporary expansion location operated by the hospital during the PHE, to be a provider-based department (PBD) of the hospital, so long as the hospital can ensure the location meets all the conditions of participation, to the extent they are not waived. In light of the need for infection control and a desire for continuity of behavioral health care and treatment services, we recognized the ability of the hospital's clinical staff to continue to deliver these services even when the beneficiary is not physically located in the hospital. Therefore, in the May 8th COVID–19 IFC (85 FR 27564), we made clear that when a hospital's clinical staff are furnishing hospital outpatient mental health services, education, and training services to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met. We referred to this policy as Hospitals without Walls (HWW). We reminded readers that the physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

3. Comment Solicitation in the CY 2022 OPPS/ASC Rule

In the CY 2022 OPPS/ASC proposed rule (86 FR 63748 through 63750) we sought comment on the extent to which hospitals have been relying on the HWW policy to bill for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital. We stated that, given that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care through use of that technology, we were interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes.

We sought comment on the extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE and whether they would anticipate continuing demand for this model of care following the conclusion of the PHE. We sought comment on whether, during the PHE, hospitals have experienced a similar increase in utilization of mental health services provided by hospital staff to beneficiaries in their homes through communications technology. We also sought comment on whether there are changes commenters believe CMS should make to account for shifting patterns of practice that rely on communications technology to provide mental health services to beneficiaries in their homes.

In response to our comment solicitation, we received approximately 60 comments that were predominantly in support of continuing OPPS payment for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital through the use of communications technology as a permanent policy post-PHE. These comments stated that the expansion of virtual care broadly during the PHE has been instrumental in maintaining and expanding access to mental health services during the PHE.

4. Current Crisis in Mental Health and Substance Use Disorder

During the COVID–19 pandemic, the number of adults reporting adverse behavioral health conditions has increased sharply, with higher rates of depression, substance use, and self-reported suicidal thoughts observed in racial and ethnic minority groups.[130] According to CDC data ''[d]uring August 19, 2020–February 1, 2021, the percentage of adults with symptoms of an anxiety or a depressive disorder during the past 7 days increased significantly (from 36.4% to 41.5%), as did the percentage reporting that they needed but did not receive mental health counseling or therapy during the past 4 weeks (from 9.2% to 11.7%)''.[131]

[130] *https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm.*

[131] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm.*

In addition to the mental health crisis exacerbated by the COVID–19 pandemic, the United States is currently in the midst of an ongoing opioid PHE, which was first declared on October 26, 2017 by former Acting Secretary Eric D. Hargan, and most recently renewed by Secretary Xavier Becerra on April 4, 2022, and is facing an overdose crisis as a result of rising polysubstance use, such as the co-use of opioids and psychostimulants (for example, methamphetamine, cocaine). Recent CDC estimates of overdose deaths now exceed 107,000 for the 12-month period ending in December 2021,[132] with overdose death rates surging among Black and Latino Americans.[133] While overdose deaths were already increasing in the months preceding the COVID–19 pandemic, the latest numbers suggest an acceleration of overdose deaths during the pandemic. Recent increases in overdose deaths have reached historic highs in this country.[134] According to information provided to CMS by interested parties, these spikes in substance use and overdose deaths reflect a combination of increasingly deadly illicit drug supplies, as well as treatment disruptions, social isolation, and other hardships imposed by the COVID–19 pandemic; but they also reflect the longstanding inadequacy of our healthcare infrastructure when it comes to preventing and treating substance use disorders (SUD) (for example, alcohol, cannabis, stimulants and opioid SUDs). Even before the COVID–19 pandemic began, in 2019, more than 21 million Americans aged 12 or over needed treatment for a SUD in the past year, but only about 4.2 million of them received any treatment or ancillary services for it.[135]

According to the Commonwealth Fund, the provision of behavioral health services via communications technology has a robust evidence base; and numerous studies have demonstrated its effectiveness across a range of modalities and mental health diagnoses (for example, depression, SUD). Clinicians furnishing tele-psychiatry services at Massachusetts General Hospital Department of Psychiatry during the PHE observed several advantages of the virtual format for furnishing psychiatric services, noting that patients with psychiatric pathologies that interfere with their ability to leave home (for example, immobilizing depression, anxiety, agoraphobia, and/or time consuming obsessive-compulsive rituals) were able to access care more consistently since eliminating the need to travel to a psychiatry clinic can increase privacy and therefore decrease stigma-related barriers to treatment. This flexibility could potentially bring care to many more patients in need, as well as enhance ease of scheduling, decrease rate of no shows, increase understanding of family and home dynamics, and protect patients and practitioners with underlying health conditions.[136]

5. CY 2023 OPPS Proposal To Pay for Mental Health Services Furnished Remotely by Hospital Staff

a. Designation of Mental Health Services Furnished to Beneficiaries in Their Homes as Covered OPD Services

During the PHE for COVID–19, many beneficiaries may be receiving mental health services in their homes from a clinical staff member of a hospital or CAH using communications technology under the flexibilities we adopted to permit hospitals to furnish these services. After the PHE ends, absent changes to our regulations, the beneficiary would need to physically travel to the hospital to continue receiving these outpatient hospital services from hospital clinical staff. We are concerned that this could have a negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided remotely by hospital staff and, during the PHE, have become accustomed to receiving these services in their homes. We are also concerned about potential disruptions to continuity of care in instances where beneficiaries' inability to continue receiving these mental health services in their homes would lead to loss of access to a specific practitioner with whom they have established clinical relationships. We believe that, given the current mental health crisis, the consequences of loss of access could potentially be severe. We also note that beneficiaries' ability to receive mental health services in their homes may help expand access to care for beneficiaries who prefer additional privacy for the treatment of their condition. We also believe that, given the changes in payment policy for mental health services via telehealth by physicians and practitioners under the PFS and mental health visits furnished by staff of RHCs and FQHCs, using interactive, real-time telecommunications technology, it is important to maintain consistent payment policies across settings of care so as not to create payment incentives to furnish these services in a specific setting.

Therefore, we propose to designate certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by clinical staff of a hospital using communications technology to beneficiaries in their homes as hospital outpatient services that are among the ''covered OPD services'' designated by the Secretary as described in section 1833(t)(1)(B)(i) of the Act and for which payment is made under the OPPS. To effectuate payment for these services, we propose to create OPPS-specific coding to describe these services. The proposed code descriptors specify that the beneficiary must be in their home and that there is no associated professional service billed under the PFS. We note that, consistent with the conditions of participation for hospitals at 42 CFR 482.11(c), all hospital staff performing these services must be licensed to furnish these services consistent with all applicable State laws regarding scope of practice. We also propose that the hospital clinical staff be physically located in the hospital when furnishing services remotely using communications technology for purposes of satisfying the requirements at 42 CFR 410.27(a)(1)(iii) and § 410.27(a)(1)(iv)(A), which refer to covered therapeutic outpatient hospital services incident to a physician's or nonphysician practitioner's service as being ''in'' a hospital outpatient department. We are seeking comment on whether requiring the hospital clinical staff to be located in the hospital when furnishing the mental health service remotely to the beneficiary in their home would be overly burdensome or disruptive to existing models of care delivery developed during the PHE, and whether we should revise the regulatory text in the provisions cited above to remove references to the practitioner being ''in'' the hospital outpatient department.

[132] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[133] Drake, J., Charles, C., Bourgeois, J.W., Daniel, E.S., & Kwende, M. (January 2020). Exploring the impact of the opioid epidemic in Black and Hispanic communities in the United States. Drug Science, Policy and Law. doi:10.1177/2050324520940428.

[134] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[135] Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20–07–01–001, NSDUH Series H–55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/.*

[136] *https://www.commonwealthfund.org/blog/2020/using-telehealth-meet-mental-health-needsduring-covid-19-crisis.*

Please see Table 47 for the proposed codes and their descriptors.

Table 47: C-CODE NUMBERS AND PROPOSED LONG DESCRIPTORS

HCPCS Code	Proposed Long Descriptor
CXX78	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
CXX79	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
CXX80	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service)

When beneficiaries are in their homes and not physically within the hospital, we do not believe that the hospital is accruing all the costs associated with an in-person service and as such the full OPPS rate may not accurately reflect these costs. We believe that the costs associated with hospital clinical staff remotely furnishing a mental health service to a beneficiary who is in their home using communications technology more closely resembles the PFS payment amount for similar services when performed in a facility, which reflects the time and intensity of the professional work associated with performing the mental health service but does not reflect certain practice expense costs, such as clinical labor, equipment, or supplies.

Therefore, we propose to assign HCPCS codes CXX78 and CXX79 to APCs based on the PFS facility payment rates for CPT codes 96159 (Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)) and 96158 (Health behavior intervention, individual, face-to-face; initial 30 minutes), respectively. We believe that the APC series that is most clinically appropriate would be the Health and Behavior Services APC series. For CY 2022, CPT code 96159 has a PFS facility payment rate of around $20 while CPT code 96158 has a PFS facility payment rate of around $60. If we use these PFS payment rates to approximate the costs associated with furnishing CXX78 and CXX79, these codes should be placed in APC 5821 (Level 1 Health and Behavior Services) and APC 5822 (Level 2 Health and Behavior Services), respectively. As CXX80 is an add-on code, payment would be packaged; and the code would not be assigned to an APC. See Table 48 for proposed SI and APC assignments and payment rates for HCPCS codes CXX78–CXX80.

TABLE 48: PROPOSED SI, APC ASSIGNMENT AND GEOMETRIC MEAN COST FOR HCPCS CODE CXX78-CXX80

HCPCS Code	Short Descriptor	Proposed SI	Proposed Proxy Service	PFS Facility Rate	Proposed APC	APC GMC
CXX78	HOPD mntl hlt, 15-29 min	S	96159	$19.52	5821	$30.48
CXX79	HOPD mntl hlt, 30-60 min	S	95158	$56.56	5822	$77.67
CXX80	HOPD mntl hlt, ea addl	N	N/A	N/A	N/A	N/A

We are seeking comment on the designation of mental health services furnished remotely to beneficiaries in their homes as covered OPD services payable under the OPPS, and on these proposed codes, their proposed descriptors, the proposed HCPCS codes and PFS facility rates as proxies for hospital costs, and the proposed APC assignments for the proposed codes. We recognize that, while mental health services have been paid under the OPPS when furnished by hospital staff in-person to beneficiaries physically located in the hospital, the ability to provide these services remotely via communications technology when the beneficiary is at home is a new model of care delivery and that we could benefit from additional information to assist us to appropriately code and pay for these services. We invite additional information from commenters on all aspects of this proposal. We will also monitor uptake of these services for any potential fraud and/or abuse. Finally, we note this proposal would also allow these services to be billed by CAHs, even though CAHs are not paid under the OPPS.

b. Periodic In-Person Visits

Section 123(a) of the CAA, 2021 also added a new subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a Medicare telehealth service furnished in the patient's home for purposes of diagnosis, evaluation, or treatment of a mental health disorder unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within six months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate. In the CY 2022 PFS final rule, we finalized that, after the first mental health telehealth service in the patient's home, there must be an in-person, non-telehealth service within 12 months of each mental health telehealth service—but also finalized a policy to allow for limited exceptions to the requirement. Specifically, if the patient and practitioner agree that the benefits of an in-person, non-telehealth service within 12 months of the mental health telehealth service are outweighed by risks and burdens associated with an in-person service, and the basis for that decision is documented in the patient's medical record, the in-person visit requirement will not apply for that 12-month period (86 FR 65059). We finalized identical in-person visit requirements for mental health visits furnished through communications technology for RHCs and FQHCs.

In the interest of maintaining similar requirements between mental health visits furnished by RHCs and FQHCs via communications technology, mental health telehealth services service under the PFS, and mental health services furnished remotely under the OPPS, we propose to require that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely; and that there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. We also propose the same exceptions policy as was finalized in the CY 2022 PFS final rule, specifically, that we would permit exceptions to the requirement that there be an in-person service without the use of communications technology within 12 months of each remotely furnished mental health service when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits of it. Exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. Hospitals must also document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies.

Section 304(a) of Division P, Title III, Subtitle A of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022) amended section 1834(m)(7)(B)(i) of the Act to delay the requirement that there be an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and at subsequent intervals as determined by the Secretary, until the 152nd day after the emergency period described in section 1135(g)(1)(B) (the PHE for COVID–19) ends. In addition, Section 304 of the CAA, 2022, delayed until 152 days after the end of the PHE similar in-person visit requirements for remotely furnished mental health visits furnished by RHCs and FQHCs. In the interest of continuity across payment systems so as to not create incentives to furnish mental health services in a given setting due to a differential application of additional requirements, and to avoid any burden associated with immediate implementation of the proposed in-person visit requirements, we propose that the in-person visit requirements would not apply until the 152nd day after the PHE for COVID–19 ends.

c. Audio-Only Communication Technology

Section 1834(m) of the Act outlines the requirements for PFS payment for Medicare telehealth services that are furnished via a ''telecommunications system,'' and specifies that, only for purposes of Medicare telehealth services furnished through a Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term ''telecommunications system'' includes asynchronous, store-and-forward technologies. We further defined the term, ''telecommunications system,'' in the regulation at § 410.78(a)(3) to mean an interactive telecommunications system, which is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communications between the patient and distant site physician or practitioner.

During the PHE for COVID–19, we used waiver authority under section 1135(b)(8) of the Act to temporarily waive the requirement, for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits, that telehealth services must be furnished using an interactive telecommunications system that includes video communications technology. Therefore, for certain services furnished during the PHE for COVID–19, we make payment for these telehealth services when they are furnished using audio-only communications technology. In the CY 2022 PFS final rule, we stated that, given the generalized shortage of mental health care professionals,[137] and the existence of areas and populations where there is limited access to broadband due to geographic or socioeconomic challenges, that we believed beneficiaries may have come to rely upon the use of audio-only communications technology in order to receive mental health services, and that a sudden discontinuation of this

[137] *https://bhw.hrsa.gov/data-research/review-health-workforceresearch.*

flexibility at the end of the PHE could have a negative impact on access to care (86 FR 65059). Due to these concerns, we modified the definition of interactive telecommunications system in § 410.78(a)(3) for services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home to include two-way, real-time audio-only communications technology in instances where the physician or practitioner furnishing the telehealth service is technically capable to use telecommunications technology that includes audio and video, but the beneficiary is not capable of, or did not consent to, use two-way, audio/video technology. We stated that we believed that this requirement will ensure that mental health services furnished via telehealth are only conducted using audio-only communications technology in instances where the use of audio-only technology is facilitating access to care that would be unlikely to occur otherwise, given the patient's technological limitations, abilities, or preferences (86 FR 65062). We also made a conforming change for purposes of furnishing mental health visits through telecommunications technology for RHCs and FQHCs. We limited payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communications technology in instances where the beneficiary is not capable of, or does not wish to use, two-way, audio/video technology.

In order to maximize accessibility for mental health services, particularly for beneficiaries in areas with limited access to broadband infrastructure, and in the interest of policy continuity across payment systems so as to not create incentives to furnish mental health services in a given setting due to a differential application of additional requirements, we propose a similar policy for mental health services furnished remotely by hospital clinical staff to beneficiaries in their homes through communications technology. Specifically, we propose that hospital clinical staff must have the capability to furnish two-way, audio/video services but may use audio-only communications technology given an individual patient's technological limitations, abilities, or preferences.

B. Comment Solicitation on Intensive Outpatient Mental Health Treatment, Including Substance Use Disorder (SUD) Treatment Furnished by Intensive Outpatient Programs (IOPs)

There are a range of services described by existing coding under the PFS and OPPS that can be billed for treatment of mental health conditions, including SUD, such as individual, group, and family psychotherapy. Over the past several years, in collaboration with interested parties and the public, we have provided additional coding and payment mechanisms for mental health care services paid under the PFS and OPPS. For example, in the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD) (HCPCS codes G2086–G2088). In the CY 2021 PFS final rule, we finalized expanding the bundled payments described by HCPCS codes G2086–G2088 to be inclusive of all SUDs (85 FR 84642 through 84643). These services are also paid under the OPPS.

Additionally, in the CY 2020 PFS final rule (84 FR 62630 through 62677), we implemented coverage requirements and established new codes describing bundled payments for episodes of care for the treatment of OUD furnished by Opioid Treatment Programs (OTPs). Medicare also covers services furnished by inpatient psychiatric facilities and partial hospitalization programs (PHP). PHP services can be furnished by a hospital outpatient department or a Medicare-certified Community Mental Health Center (CMHC). PHPs are structured to provide intensive psychiatric care through active treatment that utilizes a combination of the clinically recognized items and services described in § 1861(ff) of the Social Security Act (the Act). According to the Medicare Benefit Policy Manual, Chapter 6, Section 70.3, the treatment program of a PHP closely resembles that of a highly structured, short-term hospital inpatient program and is at a level more intense than outpatient day treatment or psychosocial rehabilitation. PHPs work best as part of a community continuum of mental health services, which range from the most restrictive inpatient hospital setting to less restrictive outpatient care and support.

We understand that, in some cases, people who do not require a level of care for mental health needs that meets the standards for PHP services nonetheless require intensive services on an outpatient basis. For example, according to SAMHSA's *Advisory on Clinical Issues in Intensive Outpatient Treatment for Substance Use Disorders,* IOP programs for substance use disorders (SUDs) offer services to clients seeking primary treatment; step-down care from inpatient, residential, and withdrawal management settings; or step-up treatment from individual or group outpatient treatment. IOP treatment includes a prearranged schedule of core services (*e.g.,* individual counseling, group therapy, family psychoeducation, and case management) for a minimum of nine hours per week for adults or six hours per week for adolescents. SAMSHA further states that the 2019 National Survey of Substance Abuse Treatment Services reports that 46 percent of SUD treatment facilities offer IOP treatment.[138]

We are seeking comment on whether these services are described by existing CPT codes paid under the OPPS, or whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs, for Medicare beneficiaries. We are also interested in additional, detailed information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, the range of practitioner types that typically furnish those services, and any other relevant information, especially to the extent it would inform our ability to ensure that Medicare beneficiaries have access to this care.

C. Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology

In the interim final rule with comment period titled ''Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency'' published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D) to provide that, during a Public Health Emergency as defined in § 400.200, the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation (PR), cardiac rehabilitation (CR), and intensive cardiac rehabilitation (ICR) services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. Specifically, the required direct physician supervision can be provided

[138] *https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep20-02-01-021.pdf.*

through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(D) in the CY 2021 OPPS/ASC final rule with comment period to provide that this flexibility continues until the later of the end of the calendar year in which the PHE as defined in § 400.200 ends or December 31, 2021 (85 FR 86113 and 86299). In the CY 2021 OPPS/ASC final rule with comment period we also clarified that this flexibility excluded the presence of the supervising practitioner via audio-only telecommunications technology (85 FR 86113).

In the CY 2022 PFS final rule, CMS added CPT codes 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)) and 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)) and HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session) to the Medicare Telehealth Services List on a Category 3 basis (86 FR 65055). These services will not be able to be furnished as Medicare telehealth services to beneficiaries in their homes after the PHE ends because of the statutory restrictions at section 1834(m)(4)(C)(ii) of the Act on eligible originating sites. However, the inclusion of these codes on the Medicare Telehealth Services List will enable payment for these services when furnished in full using two-way, audio/video communications technology when the beneficiary is in a medical setting that can serve as a telehealth originating site and meet the geographic requirements specified in section 1834(m)(4)(C). These services will remain on the Medicare Telehealth Services List through the end of CY 2023.

In order to effectuate a similar policy under the OPPS, where PR, CR and ICR rehabilitation services currently may be furnished during the PHE to beneficiaries in hospitals under direct supervision of a physician where the supervising practitioner is immediately available to be present via two-way, audio/video communications technology, we are seeking comment on whether we should continue to allow direct physician supervision for these services to include presence of the supervising practitioner physician via two-way, audio/video communication technology through the end of CY 2023. We also are seeking comment on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.

D. Use of Claims Data for CY 2023 OPPS and ASC Payment System Ratesetting Due to the PHE

As described in section I.A of this proposed rule, section 1833(t) of the Act requires the Secretary to annually review and update the payment rates for services payable under the Hospital OPPS. Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and to revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (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.

When updating the OPPS payment rates and system for each rulemaking cycle, we primarily use two sources of information: the outpatient Medicare claims data and Healthcare Cost Report Information System (HCRIS) cost report data. The claims data source is the Outpatient Standard Analytic File, which includes final action Medicare outpatient claims for services furnished in a given calendar year. For the OPPS ratesetting process, our goal is to use the best available data for ratesetting to accurately estimate the costs associated with furnishing outpatient services and set appropriate payment rates. Ordinarily, the best available claims data are the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2023 OPPS/ASC proposed rule ratesetting, the best available claims data would typically be the CY 2021 calendar year outpatient claims data processed through December 31, 2021. The cost report data source is typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file as we begin the ratesetting process. The best available cost report data used in developing the OPPS relative weights would ordinarily be from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking. For example, under ordinary circumstances, for CY 2023 OPPS ratesetting, that would be cost report data from HCRIS extracted in December 2021, which would contain many cost reports ending in FY 2020 and 2021 based on each hospital's cost reporting period.

As discussed in the CY 2022 OPPS final rule with comment period, the standard hospital data we would have otherwise used for purposes of CY 2022 ratesetting included significant effects from the COVID–19 PHE, which led to a number of concerns with using this data for CY 2022 ratesetting (86 FR 63751 through 63754). In section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190), we noted a number of changes in the CY 2020 OPPS claims data we would ordinarily use for ratesetting, likely as a result of the PHE. These changes included overall aggregate decreases in claims volume (particularly those associated with visits); significant increases in HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims; and increases in certain PHE-related services, such as HCPCS code C9803, which describes COVID–19 specimen collection and services assigned to APC 5801 (Ventilation Initiation and Management). As a result of the effects we observed from COVID–19 PHE-related factors in our claims and cost report data, as well as the increasing number of Medicare beneficiaries vaccinated against COVID–19, which we believed might make the CY 2022 outpatient experience closer to CY 2019 rather than CY 2020, we believed that CY 2020 data were not the best overall approximation of expected outpatient hospital services in CY 2022. Instead, we believed that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, were a better approximation of expected CY 2022 hospital outpatient services. Therefore, in the CY 2022 OPPS/ASC final rule with comment period, we established a policy of using CY 2019 claims data and cost reports prior to the PHE in ratesetting for the CY 2022 OPPS with certain limited exceptions, such as where CY 2019 data were not available (86 FR 63753 through 63754).

Given the effects the virus that causes COVID–19 has had on Medicare claims and cost report data the last 2 years, coupled with the expectation for future variants, we believe that it is reasonable to assume that there will continue to be some limited influence of COVID–19 PHE effects on the data we use for ratesetting. We reviewed the CY 2021 claims data available for CY 2023 OPPS ratesetting, similar to the review we conducted for CY 2022 OPPS ratesetting, to determine the degree to which the effects of the COVID–19 PHE

had continued or subsided in our claims data as well as what claims and cost report data would be appropriate for CY 2023 OPPS ratesetting. In general, we continue to see limited effects of the PHE, with service volumes generally about halfway between those in the CY 2019 (pre-PHE) claims and CY 2020 (beginning of the PHE) claims. At the aggregate level, there continues to be a decrease in the overall volume of outpatient hospital claims during the PHE, with approximately 10 percent fewer claims usable for ratesetting purposes when compared to the CY 2019 outpatient claims volume. This number compares to the 20 percent reduction that we observed last year in the CY 2020 claims. Similarly, this moderate return to more normal volumes extends across claims volume and applies to a majority of the clinical APCs in the OPPS, suggesting that, while clinical and billing patterns have not quite returned to their pre-PHE levels, they are beginning to do so.

Similar to what we observed in CY 2022 OPPS ratesetting, we continue to see broad changes as a result of the PHE, including in the APCs for hospital emergency department and clinic visits. Among those APCs, the decrease in volume was approximately 20 percent, some of which may be related to changing practice patterns during the PHE. For example, we saw a significant increase in the use of the HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims during the first year of the PHE, with approximately 35,000 services billed in the CY 2019 OPPS claims and 2.1 million services billed in the CY 2020 OPPS claims. However, in the CY 2021 OPPS claims currently available for ratesetting, we see a slight decline in volume to about 1.6 million services, noting that we would expect slightly more claims in the final rule data. Our view is that a large part of the volume increase in CY 2020 was the result of site of service changes due to the PHE.

In other cases, we saw claims data changes associated with specific services that were furnished more frequently during the PHE. For example, we identified two notable changes in the claims data for APC 5731 (Level 1 Minor Procedures) and APC 5801 (Ventilation Initiation and Management). In the CY 2020 claims data reviewed last year, we noted a significant increase in the services provided under APC 5801, from 10,340 units provided in CY 2019 claims to 12,802 units in the CY 2020 claims. However, in the CY 2021 claims available for NPRM ratesetting, there are only approximately 8,596 units of service provided through this APC, an amount even lower than the service volume we observed in CY 2019 claims.

In the case of APC 5731, HCPCS code C9803 was made effective for services furnished on or after March 1, 2020, through the interim final rule with comment period titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27602 through 27605) to describe COVID–19 specimen collection. In the CY 2021 claims data available for ratesetting for this proposed rule, there are approximately 1,367,531 single claims available for ratesetting purposes for HCPCS code C9803, which, if this code were included in ratesetting, would make up 93 percent of the claims used to set the payment rate for APC 5731 (Leve1 1 Minor Procedures APC). Under current policy, HCPCS code C9803 is a temporary code that was created to support increased testing solely during the COVID–19 PHE. Given that this is a temporary code only in use for the duration of the PHE, that the PHE could conclude before CY 2023, and that the large volume of services for this code in the CY 2021 claims data would dictate the payment rate for APC 5731 if we included this code in ratesetting, we do not believe including the claims data for this code in establishing CY 2023 payment rates would be appropriate. Our CY 2022 final policies on data used in ratesetting were established due to our expectation that the CY 2022 outpatient experience would be more similar to the CY 2019 claims rather than CY 2020 claims. Our proposed rule review of the data for CY 2023 OPPS ratesetting also is based on our belief of how well the claims and cost report data may relate to the CY 2023 outpatient experience. It is with similar considerations in mind and our belief that the volumes and costs associated with HCPCS code C9803 will not be reflective of the CY 2023 outpatient experience that we believe it is appropriate to exclude claims that would typically be used to model the cost of HCPCS code C9803 from ratesetting.

Based on our review of the CY 2021 outpatient claims available for ratesetting, we observed that many of the outpatient service volumes have partially returned to their pre-PHE levels. While the effects of the COVID–19 PHE remain at both the aggregate and service levels for certain services, as discussed earlier in this section and in section I.F of the FY 2023 IPPS proposed rule (87 FR 28123 through 28125), we recognize that future COVID–19 variants may have potentially varying effects. Therefore, we believe it is reasonable to assume that there will continue to be some effects of the COVID–19 PHE on the outpatient claims that we use for OPPS ratesetting, similar to the CY 2021 claims data. As a result, we propose to use the CY 2021 claims for CY 2023 OPPS ratesetting.

We propose to use cost report data for this proposed rule from the same set of cost reports we originally used in the CY 2021 OPPS/ASC final rule for ratesetting, which in most cases included cost reporting periods beginning in CY 2018. We ordinarily would have used the most updated available cost reports available in HCRIS in determining the proposed CY 2022 OPPS/APC relative weights (as discussed in greater detail in section II.E of the CY 2022 OPPS/ASC proposed rule (86 FR 42053)). As previously discussed, if we were to proceed with the standard ratesetting process of using updated cost reports, we would have used approximately 1,000 cost reports with the fiscal year ending in CY 2020, based on each hospital's cost reporting period. Under our historical process of updating cost report data, for the CY 2023 OPPS, the majority of the cost reports in our data would have cost reporting periods that overlap parts of CY 2020. Noting that we observed significant impact at the service level when incorporating these cost reports into ratesetting and the effects on billing/clinical patterns, similar to what we observed in the CY 2020 claims when reviewing them for the CY 2022 OPPS/ASC rulemaking cycle, we believe that it is appropriate to continue to use the same set of cost reports that we used in developing the CY 2021 OPPS, so as to mitigate the impact of that 2020-based data. We note that we will continue to review the updated cost report data as they are available.

We also note that, similar to the proposed IPPS outlier policy described in section II.A.4 of the addendum to the FY 2023 IPPS proposed rule (87 FR 28868), we propose to return to our historical process of using CCRs when determining the fixed-dollar amount threshold, and to adopt the charge and CCR inflation factors developed for the FY 2023 IPPS. For more detail regarding the proposed CY 2023 OPPS outlier policy, see section II.G of this proposed rule.

As a result of our expectation that the CY 2021 claims that we would typically use will be appropriate for establishing the CY 2023 OPPS, we propose to use the CY 2021 claims for the CY 2023

OPPS/ASC ratesetting process. However, we propose to use the same set of cost reports from the June 2020 cost report extract, which contains only pre-PHE data, to remove the effect of the PHE cost report data on estimated service cost. In addition, we propose to exclude from ratesetting claims that would be used to model the estimated cost of HCPCS code C9803 in this proposed rule.

We are also considering the alternative of continuing with our standard process of using the most updated claims and cost report data available. While the CY 2021 claims used in ratesetting would be the same as under our proposal, under this alternative our cost reports would also be updated for the most recent extract we typically would use: cost report data extracted from HCRIS in December 2021, which in most cases included cost reporting periods beginning in CY 2018. To facilitate comment on the alternative proposal for CY 2023, we are making available the cost statistics and addenda utilizing the CY 2021 claims and updated cost report data we would ordinarily have provided in conjunction with the CY 2023 OPPS/ASC proposed rule. We have provided all relevant files that would have changes calculated under this alternative approach including: the OPPS Impact File, cost statistics files, and addenda. The files specific to this alternative configuration will be identified by the word ''Alternative'' in the filenames, similar to our approach in the CY 2022 OPPS/ASC proposed and final rules. We note that the primary change as a result of the alternative proposed methodology would be in the scaled weights, which are displayed in the addenda. We refer the reader to the CMS website for the CY 2023 OPPS/ASC proposed rule for more information on where these supplemental files may be found.

E. Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients

1. Background

The regulation at 42 CFR 410.32 provides the conditions of Medicare Part B payment for diagnostic tests. Section 410.32(b) provides the supervision requirements for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests paid under the PFS. Prior to 2020, the regulation allowed only physicians as defined under Medicare law to supervise the performance of these diagnostic tests.

In the interim final rule with comment period published on May 8, 2020, in the **Federal Register** titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (the May 8th COVID–19 IFC) (85 FR 27550, 27555 through 27556, 27620), we revised § 410.32(b)(1) to allow, for the duration of the PHE, certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) to supervise the performance of diagnostic tests to the extent they were authorized to do so under their scope of practice and applicable State law.

In the CY 2021 PFS final rule (85 FR 84590 through 84492, 85026), we further revised § 410.32(b)(1) to make the revisions made by the May 8th COVID–19 IFC permanent and to add certified registered nurse anesthetists to the list of nonphysician practitioners permitted to provide supervision of diagnostic tests to the extent authorized to do so under their scope of practice and applicable State law.

As we explained in those final rules, the basis for making these revisions was to both ensure that an adequate number of health care professionals were available to support critical COVID–19-related and other diagnostic testing needs and provide needed medical care during the PHE and to implement policy consistent with section 5(a) of the President's Executive Order 13890 on ''Protecting and Improving Medicare for Our Nation's Seniors'' (84 FR 53573, October 8, 2019, E.O. 13890), which directed the Secretary to identify and modify Medicare regulations that contained more restrictive supervision requirements than existing scope of practice laws, or that limited healthcare professionals from practicing at the top of their license. We refer readers to the May 8th COVID–19 IFC (85 FR 27555 through 27556, 27620) and CY 2021 PFS final rule (85 FR 84590 through 84492, 85026) for a more detailed discussion of the reasoning behind our revisions to § 410.32.

Section 410.32(b)(1), titled ''Basic rule,'' states that ''. . .all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife.'' Section 410.32(b)(2) provides a list of services that are excepted from the basic rule in § 410.32(b)(1). Section 410.32(b)(3) defines the levels of supervision referenced in § 410.32(b)(1): general supervision (§ 410.32(b)(3)(i)); direct supervision (§ 410.32(b)(3)(ii)); and personal supervision (§ 410.32(b)(3)(iii)). Within these three definitions, only the definition for direct supervision indicates that a ''supervising practitioner'' other than a physician can provide the required supervision. The definitions for general and personal supervision continue to refer only to a physician providing the required level of supervision. Although the definitions of general and personal supervision do not specify that a ''supervising practitioner'' could furnish these levels of supervision, the above-described revisions to the ''basic rule'' governing supervision of diagnostic tests at § 410.32(b)(1) allow certain nonphysician practitioners to provide general and personal supervision to the extent they are authorized to do so under their scope of practice and applicable State law.

Section 410.28 provides conditions of payment for diagnostic services under Medicare Part B provided to outpatients by, or under arrangements by, hospitals and CAHs, including specific supervision requirements under § 410.28(e) for diagnostic tests in those settings. Section 410.28(e) relies upon the definitions of general, direct (for nonhospital locations) and personal supervision at § 410.32(b)(3)(i) through (iii) by cross-referencing those definitions. As noted above, the term ''supervising practitioner'' is absent from those definitions, although the ''basic rule'' at § 410.32(b)(1) allows certain nonphysician practitioners to provide general and personal supervision to the extent they are authorized to do so under their scope of practice and applicable State law. However, § 410.32(b) is explicitly limited to ''all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule,'' and § 410.28(e) does not contain any such ''basic rule'' to clarify that nonphysician practitioners can provide general and personal supervision.

2. Proposed Revisions to 42 CFR 410.28 and § 410.27

For purposes of clarity and consistency, we propose to revise § 410.28(e) to clarify that the same nonphysician practitioners that can provide general and personal

supervision of diagnostic testing services payable under the PFS under § 410.32(b) can provide supervision of diagnostic testing services furnished to outpatients by hospitals or CAHs. Specifically, we propose to revise our existing supervision requirements at § 410.28(e) to clarify that nurse practitioners, clinical nurse specialists, physician assistants, certified registered nurse anesthetists and certified nurse midwives may provide general, direct, and personal supervision of outpatient diagnostic services to the extent that they are authorized to do so under their scope of practice and applicable State law.

We also propose to replace the cross-references at § 410.28(e) to the definitions of general, direct (for outpatient services provided at a nonhospital location), and personal supervision at § 410.32(b)(3)(i) through (iii) with the text of those definitions as newly designated paragraphs (1), (2)(i), (2)(ii), (2)(iii), and (3) so that they are now contained within § 410.28.

Similarly, since § 410.27, which provides the supervision requirements for therapeutic outpatient hospital and CAH services, also relies on the definitions of general and personal supervision at § 410.32(b)(3)(i) and (iii), we propose to replace the cross-references at § 410.27(a)(1)(iv)(A) and (B) with the text of those definitions so that they are now contained within § 410.27. Additionally, for clarity we propose to designate the existing definition of direct supervision and the proposed definition of personal supervision at § 410.27(a)(1)(iv)(B) as § 410.27(a)(1)(iv)(B)*(1)* and *(2),* respectively. Finally, since § 410.27(a)(1)(iv)(B) and (D) contain duplicate definitions for direct supervision, we propose to remove § 410.27(a)(1)(iv)(D) in its entirety and add its language regarding pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services and the virtual presence of a physician through audio/video real-time communications technology during the PHE to the newly designated § 410.27(a)(1)(iv)(B)*(1).*

F. Coding and Payment for Category B Investigational Device Exemption Clinical Devices and Studies

1. Medicare Coverage of Items and Services in FDA-Approved Investigational Device Exemption Clinical Studies

Section 1862(m) of the Act (as added by section 731(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) allows for Medicare payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study. Under the general rulemaking authority under section 1871 of the Act, CMS finalized changes to the IDE regulations (42 CFR 405 Subpart B), effective January 1, 2015 (78 FR 74809). CMS added criteria for coverage of IDE studies and changed from local Medicare Administrative Contractor (MAC) review and approval of IDE studies to a centralized review and approval of IDE studies.

2. Background on Medicare Payment for FDA-Approved IDE Studies

Medicare may make payment for routine care items and services furnished in an FDA-approved Category A (Experimental) study if CMS determines that the Medicare coverage IDE study criteria in 42 CFR 405.212 are met. However, Medicare does not make payment for the Category A device, which is excluded from coverage by 1862(a) of the Act. A Category A (Experimental) device refers to a device for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

As described in § 405.211(b), with regard to a Category B (Nonexperimental/investigational) IDE study, Medicare may make payment for the Category B device and the routine care items and services in the study if CMS determines that the Medicare coverage IDE study criteria in § 405.212 are met. A Category B (Non-experimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type (§ 405.201(b)).

3. Proposal for Coding and Payment for Category B IDE Devices and Studies

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61223 through 61224), we created a temporary HCPCS code to describe the V-Wave Interatrial Shunt Procedure, including the cost of the device, for the experimental group and the control group of the study after hearing concerns from interested parties that current coding for the V-Wave procedure would compromise the scientific validity of the study. Specifically, for that randomized, double-blinded control Category B IDE study, all participants received a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also received the V-Wave interatrial shunt procedure while participants assigned to the control group only received right heart catheterization. We stated that the developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the Category B IDE device—the interatrial shunt—because an additional procedure code would be included on the claims for participants receiving the interatrial shunt. Therefore, we created a temporary HCPCS code to describe the V-Wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved IDE study) to describe the service, including the cost of the device, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 ($10,001–$15,000)).

In addition to the previously described procedure and the creation of HCPCS code C9758, CMS has created similar codes and used similar payment methodologies for other similar IDE studies. For example, the following HCPCS codes were also created and described blinded procedures, including the cost of the device, in which both the active treatment and placebo groups are described by the same HCPCS code: HCPCS code C9782 (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (*e.g.,* mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including

ventriculography, all laboratory services, and all imaging with or without guidance (*e.g.,* transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study), and HCPCS code C9783 (Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catherization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved Investigational Device Exemption (IDE) study).

For CY 2023, we propose to make a single blended payment, and establish a new HCPCS code or revise an existing HCPCS code for devices and services in Category B IDE studies when the Medicare coverage IDE study criteria at § 405.212 are met and where CMS determines, that a new or revised code and/or payment rate is necessary to preserve the scientific validity of such a study. We intend that this proposal would preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned. For example, it is expected that in a typical study, those receiving the placebo may have a lesser Medicare payment due to absence of the Category B device, and therefore, the payment amount may unblind the study and compromise its scientific validity. As has occurred previously, we anticipate interested parties will engage with us and notify us, for instance, if they have concerns that an existing HCPCS code may compromise the scientific validity of a Category B IDE study.

Therefore, we propose to create a new HCPCS code or revise an existing HCPCS code to describe a Category B IDE device and study, which would include both the treatment and control arms and related device(s), as well as routine care items and services as specified under § 405.201, if we determine it is necessary to do so to preserve the scientific validity of the study; we would assign the new or revised code a blended payment rate. We would do this where the coding would compromise the scientific validity of the study. The single blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to placebo. For example, in a study, for which CMS determines the Medicare coverage IDE study criteria in § 405.212 are met and where there is a 1:1 assignment of the device to placebo (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the placebo in a 1:1 ratio. Furthermore, costs for routine care items and services, as specified under § 405.201 in the study would be included in the single blended payment.

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 to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other information and factors. Consistent with this requirement, we propose this policy to ensure we pay appropriately under the OPPS for Category B IDE devices and studies in a manner that preserves the studies' scientific validity. This proposal is similar to our standard practice of setting payment rates based on the frequency of resources used. Our proposal to create new HCPCS codes or revise existing HCPCS codes to operationalize our proposal to make a single payment for the blended cost of the device depending on the frequency with which it is used in the study, together with the study costs, is consistent with our historical practice of creating new codes for OPPS and ASC programmatic needs. We note that, in addition to our general authority to review and revise the APC groups and the relative payment weights in section 1833(t)(9)(A) of the Act, section 1833(w) of the Act is additional authority that would support our proposal. In particular, section 1833(w) of the Act authorizes the Secretary to develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under section 1833, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies. For example, Medicare may make an alternative method of payment for items and services provided under clinical trials where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design. We are inviting comments on our proposal.

4. Proposed Coding and Payment for Category B IDE Studies Regulation Text Changes

We propose to codify our proposed process of utilizing a single packaged payment for Category B IDE studies, including the cost of the device and routine care items and services, in the regulation text for payment to hospitals in a new § 419.47. In particular, we propose to provide in new § 419.47(a) that CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which would include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201, when CMS determines that the Medicare coverage IDE study criteria at § 405.212 are met, and a new or revised code is necessary to preserve the scientific validity of the IDE study. Additionally, in a new section, § 419.47(b), we propose that when we create a new HCPCS code or revise an existing HCPCS code under proposed paragraph (a), we will make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under § 405.201. The payment would be based on the average resources utilized for each study participant. For example, the payment would account for the frequency with which the investigational device is used in the study population.

G. OPPS Payment for Software as a Service

1. Background on Clinical Software and OPPS Add-on Codes Policy

Rapid advances in innovative technology are having a profound effect on every facet of health care delivery. Novel and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve outcomes, and reduce overall costs to the program. In some cases, these innovative technologies are substituting for more invasive care and/or augmenting the practice of medicine.

New clinical software, which includes clinical decision support software, clinical risk modeling, and computer aided detection (CAD), are becoming increasingly available to providers. These technologies often perform data analysis of diagnostic images from patients. While many of these technologies are new, we note that clinical software, particularly CAD, has

been used to aid or augment clinical decision making for decades. These technologies rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition. We refer to these algorithm-driven services that assist practitioners in making clinical assessments, and that providers pay for either on a subscription or per-use basis, as Software as a Service (SaaS).

Starting in 2018, we began making payment for the SaaS procedure Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow. HeartFlow is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow SaaS procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, its use may eliminate the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the main diagnostic/image procedure (*i.e.,* the primary service). In the CY 2018 OPPS/ASC final rule, however, we determined that it was appropriate for HeartFlow to receive a separate payment because the analytics are performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan (82 FR 52422 through 52425). We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the SaaS procedure that indicated the price of the procedure was approximately $1,500. In CY 2020, we utilized our low-volume payment policy to calculate HeartFlow's arithmetic mean to assign it to New Technology APC 1511 (New Technology —Level 11 ($901-$1000)) with a payment rate of $950.00 (84 FR 61220 through 61221). We continued this APC assignment in CY 2021 and CY 2022 using our equitable adjustment authority (84 FR 85941 through 85943; 86 FR 63533 through 63535). For CY 2023, we propose to move HeartFlow (HCPCS 0503T) from New Technology APC 1511 to APC 5724 (Level 4 Diagnostic Tests and Related Services), a clinical APC, as we believe we have enough data to make an appropriate clinical APC assignment for HeartFlow. We direct readers to section III.E of this proposed rule for a more detailed discussion of the proposed Heartflow clinical APC assignment.

While HeartFlow was the first SaaS procedure for which we made separate payment under the OPPS, we have since begun paying for other SaaS procedures In CY 2021, we assigned CPT code 92229 (Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral), an artificial intelligence system to detect diabetic retinopathy known as IDx-DR to APC 5733 with the status indicator ''S'' (85 FR 85960 to 85961). IDx-DR uses an artificial intelligence algorithm to review images of a patient's retina to provide a clinical decision as to whether the patient needs to be referred to an eyecare professional for diabetic retinopathy or rescreened in twelve months (negative for mild diabetic retinopathy). Also, in CY 2021, we began paying for CPT code 0615T (Eye-movement analysis without spatial calibration, with interpretation and report), which involves the use of the EyeBOX system as an aid in the diagnosis of concussion. We assigned EyeBOX to APC 5734 with the status indicator ''Q1,'' to indicate that the code is conditionally packaged when performed with another service on the same day (85 FR 85952 to 85953).

Over the past several years, the AMA has established several codes that describe SaaS procedures. HeartFlow, IDx-DR, and the EyeBox System are each described by single CPT codes. But for a procedure known by the tradename LiverMultiScan, the CPT editorial panel created two CPT codes for CY 2022, a primary code and an add-on code:

- *0648T:* Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session.
- *0649T:* Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) (List separately in addition to code for primary procedure).

LiverMultiScan uses clinical software to aid the diagnosis and management of chronic liver disease through analysis using proprietary algorithms of MR images acquired from patients' providers. As described above, the coding for LiverMultiScan is bifurcated into CPT code 0648T, billable when LiverMultiScan is used to analyze already existing images, and CPT add-on code 0649T, describing the LiverMultiScan software analysis, which is adjunctive to the acquisition of the MR images. In accordance with our OPPS policy, we review all new CPT codes and, for those that are payable under the OPPS, we assign them to appropriate APCs and make status indicator assignments for them. In the CY 2022 OPPS/ASC final rule with comment period, we assigned CPT code 0648T to New Technology APC 1511 (86 FR 63542). Given the dependent nature and adjunctive characteristics of procedures described by add-on codes and in light of our longstanding OPPS packaging principles, payment for add-on codes is generally packaged into the primary procedure. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74942 through 74945) and in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817 through 66818), we stated that procedures described by add-on codes represent an extension or continuation of a primary procedure, which means they are ancillary, supportive, dependent, or adjunctive to a primary service. Add-on codes describe services that are always performed in addition to a primary procedure and are never reported as a stand-alone code. Because the second LiverMultiScan code—CPT code 0649T—is an add-on code, in accordance with our current OPPS policy, we packaged payment for it with the primary service with which it is furnished, rather than paying for it separately as we do for the primary LiverMultiScan code—CPT code 0648T (86 FR 63541 through 63543).

2. Recent CPT Codes for SaaS Procedures

The AMA has continued to establish new CPT codes that describe SaaS procedures using two codes: a primary code that describes the standalone clinical software service and an add-on code that describes a clinical software service that is adjunctive to and billed concurrent with a diagnostic imaging service. The standalone code is billed

when no additional imaging is required because raw images from a prior scan are available for the software to analyze, while the add-on code is billed with an imaging service when a prior imaging scan is unavailable, or the prior images are insufficient. If a patient needs a SaaS procedure and has no existing diagnostic images, the patient would undergo the diagnostic imaging (*i.e.,* CT or MRI), and the SaaS procedure. In this scenario, the provider would report the diagnostic imaging service code and the SaaS add-on code on the same day of service. In contrast, if a patient has pre-existing diagnostic images, the provider would only need to perform the SaaS procedure and would only report the standalone SaaS code.

Please see Table 49 for recent CPT codes for SaaS procedures, including LiverMultiScan. For CY 2022, the CPT Editorial Panel also established CPT codes 0721T, 0722T, 0723T, and 0724T.

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Table 49: SAAS PROCEDURE CPT CODES, LONG DESCRIPTORS, APC ASSIGNMENTS AND STATUS INDICATORS

CPT code	Trade Name	Long Descriptor	APC	Status Indicator
0648T	LiverMultiScan	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	1511	S
0649T	LiverMultiScan	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NA	N
0721T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	1508	S
0722T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure	NA	N

CPT code	Trade Name	Long Descriptor	APC	Status Indicator
		contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)		
0723T	Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	1511	S
0724T	Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NA	N

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The standalone codes associated with LiverMultiScan (CPT code 0648T), Optellum LCP (CPT code 0721T), and QMRCP (CPT code 0723T) are paid separately under the OPPS and assigned to specific APCs as described in Table 49. However, according to our existing packaging policy, we would package payment for the add-on codes, specifically, CPT codes 0649T, 0722T, and 0724T, into the associated diagnostic imaging service.

3. CY 2023 Proposal for SaaS Add-on Codes

From 2021 to 2022, we reviewed and approved New Technology applications for the LiverMultiScan, Optellum, and QMRCP SaaS procedures. LiverMultiScan was assigned to a New Technology APC effective January 1, 2022, and Optellum and QMRCP were assigned to New Technology APCs effective July 1, 2022. While the standalone codes for these services are assigned to New Technology APCs and are separately payable, applicants have informed us that the services described by the add-on codes, specifically, CPT codes 0649T, 0722T, and 0724T, should also be paid separately because the technologies are new and associated with significant costs.

Although the CPT Editorial Panel has designated these codes as add-on codes, the services described by CPT codes 0649T, 0722T, and 0724T are not consistent with our definition of add-on services. In many instances, the costs associated with the add-on codes exceed the costs of the imaging service with which they would be billed, and we believe these add-on codes describe separate and distinct services that should be paid separately, rather than as services that are ancillary, supportive, dependent, or adjunctive to a primary service into which their payment is packaged. Therefore, for CY 2023, we propose not to recognize the select CPT add-on codes that describe SaaS procedures under the OPPS and instead establish HCPCS codes, specifically, C-codes, to describe the add-on codes as standalone services that would be billed with the associated imaging service. We believe the payment for the proposed C-codes describing the SaaS procedures with add-on CPT codes, when billed concurrent with the acquisition of the images, should be equal to the payment for the SaaS procedures when the services are furnished without imaging and described by the standalone CPT code because the SaaS procedure is the same regardless of whether it is furnished with or without the imaging service. Therefore, we propose the C-codes be assigned to identical APCs and have the same status indicator assignments as their standalone codes.

For the LiverMultiScan service, we propose not to recognize CPT code 0649T under the OPPS and instead propose to establish C97X1 to describe the analysis of the quantitative magnetic resonance images that must be billed alongside the relevant CPT code describing the acquisition of the images.

Below is the proposed long descriptor for the service:

• *C97X1:* Quantitative magnetic resonance analysis of tissue composition (*e.g.,* fat, iron, water content), includes multiparametric data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with diagnostic MRI examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure).

For the Optellum LCP service, we propose not to recognize CPT code 0722T and instead propose to establish C97X2 to describe the use of Optellum LCP that must be billed alongside a concurrent CT scan. Below is the proposed long descriptor for the service:

• *C97X2:* Quantitative computed tomography (CT) tissue characterization, includes data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with concurrent CT examination of any structure contained in the acquired diagnostic imaging dataset.

For the QMRCP service, we propose not to recognize CPT code 0724T and instead propose to establish C97X3 to describe the use of QMRCP that must be billed alongside a concurrent CT scan. Below is the proposed long descriptor for the service:

• *C97X3:* Quantitative magnetic resonance cholangiopancreatography (QMRCP) includes data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure).

The proposed payment rates for C97X1, C97X2, and C97X3, as well as the standalone CPT codes that describe the same SaaS procedures, can be found in Addendum B to this proposed rule, which is available via the CMS website.

4. Comment Solicitation on Payment Policy for SaaS Procedures

Consistent with our OPPS payment policies, we review new CPT codes and determine whether the items or services described by the codes are appropriate for payment under the OPPS. For codes that are appropriate for payment, we propose the appropriate payment indicator, known as the status indicator (SI) under the OPPS, and APC assignment, according to our OPPS policies. We note the new SaaS procedures have been assigned Category III CPT codes by the AMA. Because we generally do not have hospital claims data for new codes, the payment indicator and APC assignments are determined based on several factors, which include but are not limited to:

• Review of resource costs and clinical similarity of the service to existing procedures;

• Input from our medical advisors; and

• Other information available to us (75 FR 71909).

Although we have begun paying separately for SaaS procedures under the OPPS relatively recently, with the HeartFlow procedure being the first separately payable SaaS procedure in CY 2018, we recognize that certain clinical decision support software, including machine learning or ''AI,'' has been available for many years. In the past ten years, clinical decision support software has been commonly used alongside electronic medical records by medical practitioners. Nonetheless, the number of FDA approved or cleared ''machine learning'' or ''AI'' clinical software programs has rapidly increased in the past few years. We note that the FDA has approved many SaaS procedures for similar functions: there are at least six software products that purport to detect findings in Computed Tomography studies of the chest.[139] Additionally, we note some clinical software developers are now using alternative licensing that charges per use rather than using the traditional annual subscription or bulk use subscription. Empirical research has shown that pay-per-use may lead to overuse of ''AI'' technology.[140] As a result of these variables and potentially others, there is significant price variation within the SaaS procedure space.

We recognize that, as described in the introduction to this section, SaaS procedures are a heterogenous group of services, which presents challenges when it comes to adopting payment policy for SaaS procedures as a whole. Due to the novel and evolving nature of these technologies, it has been challenging to compare some SaaS procedures to existing medical services for purposes of determining clinical and resource similarity.

We are therefore soliciting public comment on a payment approach that would broadly apply to SaaS procedures, including:

• How to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS;

• How to identify costs associated with these kinds of services;

• How these services might be available and paid for in other settings (physician offices, for example); and

• How we should consider payment strategies for these services across settings of care.

We are also seeking comment on the specific payment approach we might use for these services under the OPPS as SaaS-type technology becomes more widespread across healthcare which are not limited to imaging services. For example, we could consider packaging payment for the diagnostic image and the SaaS procedure under new HCPCS codes, (*i.e.,* G-codes), to efficiently and cost-effectively pay for SaaS procedures. These G-codes could broadly describe the diagnostic image service and any SaaS procedure performed. Under this approach, the OPPS would not recognize either the standalone or the add-on codes describing SaaS procedures. Instead, all associated imaging and the SaaS would be described by a single HCPCS code, which could be assigned to a relevant clinical APC. An example of this would be hypothetical code GXXX1 (Computed tomography, thorax, diagnostic; with or without contrast material and with concurrent or subsequent computed analysis of the original image for further interpretation and report using a standardized computing instrument.), which describes both diagnostic imaging and any associated SaaS for the thorax region of the body and could be assigned to APC 5573 (Level 3 Imaging with Contrast).

Alternatively, we could expand composite APCs, which provide a single payment for groups of services that are performed together, including the diagnostic imaging and SaaS procedure, during a single clinical encounter to result in the provision of a complete service.

A third approach could utilize HCPCS codes (*i.e.,* G- or C- codes) to describe both the diagnostic imaging and the SaaS procedure, and then assign the code that describes the combined services to New Technology APCs that would pay for both services.

We welcome input from interested parties on these payment approaches and any additional payment approaches that would enhance our ability to provide equitable payment for SaaS procedures while protecting the Medicare trust fund.

Finally, we are aware that bias in software algorithms has the potential to disparately affect the health of certain

[139] *https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.*

[140] *https://www.nature.com/articles/s41746–022–00609–6.pdf.*

populations.[141] Therefore, in addition to our comment solicitation on payment approaches, we are seeking comments on how we could encourage software developers and other vendors to prevent and mitigate bias in their algorithms and predictive modeling. We would also appreciate feedback on how we can accurately evaluate and ensure that the necessary steps have been taken to prevent and mitigate bias in software algorithms to the extent possible.

H. Proposed Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators

In the FY 2023 IPPS/LTCH PPS proposed rule, we requested public comments on potential IPPS and OPPS payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators (87 FR 28622 through 28625). Given the importance of NIOSH-approved surgical N95 respirators in protecting hospital personnel and beneficiaries from the SARS-CoV–2 virus and future respiratory pandemic illnesses, we indicated we were considering whether it might be appropriate to provide payment adjustments to hospitals to recognize the additional resource costs they incur to acquire NIOSH-approved surgical N95 respirators that are wholly domestically made. We stated that NIOSH-approved surgical N95 respirators, which faced severe shortage at the onset of the COVID–19 pandemic, are essential for the protection of patients and hospital personnel that interface with patients. We indicated that procurement of NIOSH-approved surgical N95 respirators that are wholly domestically made, while critical to pandemic preparedness and protecting health care workers and patients, can result in additional resource costs for hospitals.

We said we were interested in feedback and comments on the appropriateness of payment adjustments that would account for these additional resource costs. We stated that we believe such payment adjustments could help achieve a strategic policy goal, namely, sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We stated we were considering such payment adjustments for 2023 and potentially subsequent years.

As described in more detail in the sections that follow, and for the reasons discussed, we propose to make a payment adjustment under the OPPS and IPPS for the additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023.

2. General Background and Overview of Proposal

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, President Biden issued Executive Order (E.O.) 13987, titled ''Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security'' on January 20, 2021 (86 FR 7019). This order launched a whole-of-government approach to combat the coronavirus disease 2019 (COVID–19) and prepare for future biological and pandemic threats. This response has continued over the past year. In March 2022, President Biden released the National COVID–19 Preparedness Plan that builds on the progress of the prior 13 months and lays out a roadmap to fight COVID–19 in the future.[142] Both the ongoing threat of COVID–19 and the potential for future pandemics necessitate significant investments in pandemic preparedness.

Availability of personal protective equipment (PPE) in the health care sector is a critical component of this preparedness, and one that displayed significant weakness in the beginning of the COVID–19 pandemic. In spring of 2020, supply chains for PPE faced severe disruption due to lockdowns that limited production, and unprecedented demand spikes across multiple industries. Supply of surgical N95 respirators—a specific type of filtering facepiece respirator used in clinical settings—was one type of PPE that was strained in hospitals. So-called ''just-in-time'' supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough surgical N95 respirators to protect health care workers. Prices for surgical N95s soared, from an estimated $0.25–$0.40 range[143] to $5.75[144] or even $12.00 in some cases.[145] Unable to obtain surgical N95s regulated by NIOSH, hospitals had to turn to KN95s—a Chinese standard of respirator— and other non-NIOSH-approved disposable respirators that were authorized under Emergency Use Authorization (EUA). Concerns were raised during the COVID–19 pandemic regarding counterfeit respirators. NIOSH evaluates and approves surgical N95s to meet efficacy standards for air filtration and protection from fluid hazards present during medical procedures. KN95 respirators, on the other hand, are not regulated by NIOSH. KN95s have faced particular counterfeit and quality risks—with NIOSH finding that about 60 percent of KN95 respirators that it evaluated during the COVID–19 pandemic in 2020 and 2021 did not meet the particulate filter efficiency requirements that they intended to meet.[146] Failure to meet these requirements compromises safety of health care personnel and patients.

Over the course of the pandemic, U.S. industry responded to the shortages and dramatically increased production of N95s. Today, the majority of surgical N95s purchased by hospitals are assembled in the U.S., and prices have returned to rates closer to $0.70 per respirator.[147] However, risks remain to maintain preparedness for COVID–19 and future pandemics. It is important to maintain this level of domestic production for surgical N95s, which provide the highest level of protection from particles when worn consistently and properly, protecting both health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material—including the virus that causes COVID–19. Additionally, it is important as a long-term goal to ensure that a sufficient share of those surgical N95s are wholly made in the U.S.—that is, including raw materials and components. The COVID–

[141] *https://www.science.org/doi/10.1126/science.aax2342.*

[142] White House, National COVID–19 Preparedness Plan, March 2022; *https://www.whitehouse.gov/wpcontent/uploads/2022/03/NAT-COVID-19-PREPAREDNESS-PLAN.pdf.*

[143] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Supply Chain Control Tower analysis.

[144] Society for Healthcare Organization Procurement Professionals, COVID–19 PPD Cost Analysis, April 2020; *http://cdn.cnn.com/cnn/2020/images/04/16/shopp.covid.ppd.costs.analysis_.pdf.*

[145] Washington Post, ''U.S. sent millions of face masks to China early this year, ignoring pandemic warning signs,'' April 2020; *https://www.washingtonpost.com/health/us-sent-millions-of-face-masks-to-china-early-this-yearignoring-pandemic-warning-signs/2020/04/18/aaccf54a-7ff5-11ea-8013-1b6da0e4a2b7_story.html.*

[146] U.S. Centers for Disease Control and Prevention ''Types of Masks and Respirators'';*https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html.*

[147] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Supply Chain Control Tower analysis

19 pandemic has illustrated how overseas production shutdowns, foreign export restrictions, or ocean shipping delays can jeopardize availability of raw materials and components needed to make critical public health supplies. In a future pandemic or COVID–19-driven surge, hospitals need to be able to count on PPE manufacturers to deliver the equipment they need on a timely basis in order to protect health care workers and their patients. Sustaining a level of wholly domestic production of surgical N95 respirators is integral to maintaining that assurance.

This policy goal—ensuring that quality PPE is available to health care personnel when needed by maintaining production levels of wholly domestically made PPE— is emphasized in the National Strategy for a Resilient Public Health Supply Chain, published in July 2021 as a deliverable of President Biden's Executive Order 14001 on ''A Sustainable Public Health Supply Chain.'' To help achieve this goal, the U.S. Government is committing to purchase wholly domestically made PPE in line with new requirements in section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58). These new contract requirements stipulate that PPE purchased by covered departments must be wholly domestically made—that is, the products as well as their materials and components must be grown, reprocessed, reused, or produced in the U.S.

The Federal Government's procurement of wholly domestically made PPE will help achieve the stated policy goal. However, the U.S. Government alone cannot sustain the necessary level of production. As outlined in the previously mentioned National Strategy for a Resilient Public Health Supply Chain, the U.S. Government is only one small part of the market for PPE. Hospitals are the primary purchasers and users of medical PPE including surgical N95 respirators. Sustaining a strong domestic industrial base for PPE—in order to be prepared for future pandemics or COVID–19-driven surges and protect Americans' health during such times—therefore, requires hospitals' support.

Surgical N95 respirators are a particularly critical type of PPE needed to protect personnel and beneficiaries from the SARS–CoV–2 virus and future respiratory pandemic illnesses. However, wholly domestically made NIOSH-approved surgical N95 respirators are generally more expensive than foreign-made ones. Therefore, we stated in the FY 2023 IPPS/LTCH PPS proposed rule that we believe a payment adjustment that reflects, and offsets, the additional marginal costs that hospitals face in procuring wholly domestically made NIOSH-approved surgical N95 respirators might be appropriate. These marginal costs are due to higher prices for wholly domestically made NIOSH-approved surgical N95s, which, in turn, primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in countries such as China, where many N95 and other respirators are made. We stated that such a payment adjustment might provide sustained support over the long term to hospitals that purchase wholly domestically made NIOSH-approved surgical N95 respirators, and could help safeguard personnel and beneficiary safety over the long term by sustaining production and availability of these respirators.

As previously noted, in the FY 2023 IPPS/LTCH PPS proposed rule, we requested public comments on potential IPPS and OPPS payment adjustments for wholly domestically made NIOSH-approved surgical N95 respirators. We received many comments that were helpful in developing the proposed payment adjustment discussed later in this section. For instance, many commenters were supportive of a payment adjustment, acknowledging the importance of surgical N95 respirators in keeping health care workers and patients safe and attesting to the difficulties of procuring surgical N95 respirators during the height of the COVID–19 pandemic. The majority of commenters supported an approach of CMS making biweekly interim lump-sum payments that would be reconciled at cost report settlement, although some commenters preferred a claims-based approach. Many commenters urged CMS to minimize the administrative burden on hospitals in the development of any N95 payment policy. We also acknowledge the comments of MedPAC and others stating that Medicare payment policy is not the most appropriate mechanism to support domestic manufacturing of medical supplies. As discussed, because hospitals are the primary purchasers and users of medical PPE, including surgical N95 respirators, we believe a payment adjustment that reflects the additional marginal costs that hospitals face in procuring wholly domestically made NIOSH-approved surgical N95 respirators may help to sustain their domestic production and availability, and thereby help to safeguard personnel and beneficiary safety over the long term. We thank everyone who submitted comments for their feedback.

We propose to make a payment adjustment under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators, as defined in Section X.H.3 of this proposed rule, for cost reporting periods beginning on or after January 1, 2023. For the IPPS, we propose to make this payment adjustment under section 1886(d)(5)(I) of the Act, which authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. For the OPPS, we propose to make this payment adjustment under section 1833(t)(2)(E) of the Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

3. Proposed Definition of Domestic NIOSH-approved Surgical N95 Respirators

For purposes of this policy, we propose to categorize all NIOSH-approved surgical N95 respirators purchased by hospitals into two categories: (1) Domestic NIOSH-approved surgical N95 respirators; and (2) Non-domestic NIOSH-approved surgical N95 respirators.

As discussed, it is critically important to ensure that a sufficient share of surgical N95s are wholly made in the U.S.—that is, including raw materials and components. We believe that the most appropriate framework for determining if a NIOSH-approved surgical N95 respirator is wholly made in the U.S. and therefore, considered domestic for purposes of the proposed adjustments, is the Berry Amendment. The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States.[148] Berry Amendment restrictions are implemented by the DoD Federal Acquisition Regulation Supplement (DFARS) 252.225–7002, and State DOD cannot acquire specified ''items, either as end products or components, unless the items have been grown, reprocessed, reused, or produced in the United States.'' [149] Unless DOD grants a waiver

[148] *https://www.trade.gov/berry-amendment.*

[149] *https://www.trade.gov/berry-amendment-implementation.*

because domestic firms do not make the product or because other exceptions in the law are met, the entire production process of an affected product, from the production of raw materials to the manufacture of all components to final assembly, must be performed in the United States.[150]

The Berry Amendment has been critical to the viability of the textile and clothing production base in the United States and has been critical to maintaining the safety and security of our armed forces, by requiring covered items to be produced in the United States.[151] We believe that using the Berry Amendment as the basis for defining domestic NIOSH-approved surgical N95 respirators will provide similar support to U.S. surgical N95 respirator manufacturers and help ensure that quality surgical N95 respirators are available to health care personnel when needed.

Therefore, based on the Berry Amendment, we propose to define a NIOSH-approved surgical N95 respirator as domestic if the respirator and all of its components are grown, reprocessed, reused, or produced in the United States. We propose that for purposes of this policy all other NIOSH-approved surgical N95 respirators would be non-domestic.

We recognize that a hospital cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases is domestic under our proposed definition. Therefore, we propose that a hospital may rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our proposed definition. The written statement must have been certified by one of the following: (i) the manufacturer's Chief Executive Officer (CEO); (ii) the manufacturer's Chief Operating Officer (COO); or (iii) an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. The written statement, or a copy of such statement, could be obtained by the hospital directly from the manufacturer, obtained through the supplier or Group Purchasing Organization (GPO) for the hospital who obtained it from the manufacturer, or obtained by the hospital because it was included with or printed on the packaging by the manufacturer. This written statement may be required to substantiate the data included on the supplemental cost reporting form as discussed in section X.H.5 of this proposed rule. The recordkeeping requirements at current § 413.20, require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare.

4. Proposed Payment Adjustment Amount Under the IPPS and OPPS for Domestic NIOSH-approved Surgical N95 Respirators

We expect that domestic NIOSH-approved surgical N95 respirators will continue to be generally more costly than non-domestic respirators. However, it is challenging to precisely predict and quantify the future cost differences given the dynamic nature of the current marketplace and data limitations. Therefore, we propose to initially base the payment adjustments on the IPPS and OPPS shares of the estimated difference in the reasonable costs[152] of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators. These payments would be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. Under this proposal the biweekly interim lump-sum payments would be available for cost reporting periods beginning on or after January 1, 2023. Any provider could make a request for these biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (*Payments* to providers: Specific rules) and 42 CFR 412.116(c) (Special interim payments for certain costs). These payment amounts would be determined by the MAC, consistent with existing policies and procedures. In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into twenty-six equal biweekly payments. The estimated amount is based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15–1 2405.2 for additional information.) The MACs would determine the interim lump-sum payments based on the data the hospital may provide that reflects the information that will be included on the N95 supplemental cost reporting form as discussed in section X.H.5 of this proposed rule. In future years, if finalized, the MACs would determine the interim biweekly lump-sum payments utilizing information from the prior year's surgical N95 supplemental cost reporting form, which may be adjusted based on the most current data available. This would be consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance paid on interim biweekly basis as noted in CMS Pub 15–1 2405.2. As described in more detail in section X.H.5 of this proposed rule, a hospital would separately report on its cost report the aggregate cost and total quantity of domestic NIOSH-approved surgical N95 respirators and non-domestic respirators for cost reporting periods beginning on or after January 1, 2023. This information, along with existing information already collected on the cost report as shown in section X.H.5 of this proposed rule, would be used to calculate a Medicare payment for the estimated cost differential, specific to each hospital, incurred due to the purchase of domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators.

As previously discussed, for the IPPS, we propose to make this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1886(d)(5)(I) of the Act. To further support the strategic policy goal of sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency, we are not proposing to make the IPPS payment adjustment budget neutral under the IPPS.

As also previously discussed, for the OPPS, we propose to make the payment adjustment for these additional resource costs under section 1833(t)(2)(E) of the Act. Section 1833(t)(2)(E) of the Act provides that the Secretary shall establish, in a budget neutral manner, other adjustments (in addition to outlier and transitional pass-through payments) necessary to ensure equitable payments, such as adjustments for certain classes of hospitals. Consistent with this authority, the proposed OPPS payment adjustment would be budget neutral.

As we gain more experience with this payment policy, if finalized, its impact on the N95 marketplace, and the data collected, we may revisit the approach of payments based on the reasonable costs of each hospital. See the discussion in section X.H.8 of this proposed rule regarding potential future rulemaking to refine our proposed approach.

[150] *https://sgp.fas.org/crs/misc/R44850.pdf.*

[151] *https://www.trade.gov/berry-amendment.*

[152] In accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9.

5. Proposed Calculation of the OPPS and IPPS Payment Adjustments on the Cost Report

In order to calculate the N95 payment adjustment for each eligible cost reporting period, we propose to create a new supplemental cost reporting form that will collect from hospitals the additional information described in this section. This information would be used along with other information already collected on the hospital cost report to calculate IPPS and OPPS payment adjustment amounts. The information collection requirements for the proposed new supplemental cost reporting worksheet are discussed in section XXII.F of this proposed rule.

In this section we describe the information we propose to collect on the new supplemental cost reporting form and the proposed steps for determining the IPPS and OPPS payment adjustment amounts.

Step 1—Collect additional information on the new supplemental cost reporting form.

To determine the IPPS and OPPS payment adjustments, we propose to collect the following information on a new supplemental cost reporting form:

(1) Total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital.[153]

(2) Total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital.

(3) Total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.

(4) Total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.

Step 2—Calculate a hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators.

With the respirator information reported on the new supplemental cost reporting form we propose to calculate the following statistics on the new cost report form:

(1) The average cost of domestic NIOSH-approved surgical N95 respirators purchased. This would be calculated by dividing the reported total aggregate cost of the domestic NIOSH-approved surgical N95 respirators purchased by the reported total quantity of domestic NIOSH-approved surgical N95 respirators purchased. If the hospital purchased zero NIOSH-approved surgical N95 domestic respirators, this value would be set to 0.

(2) The average cost of non-domestic NIOSH-approved surgical N95 respirators purchased. This would be calculated by dividing the reported total aggregate cost of the non-domestic NIOSH-approved surgical N95 respirators purchased by the reported total quantity of non-domestic NIOSH-approved respirators purchased. If the hospital purchased zero non-domestic NIOSH-approved surgical N95 respirators, this value would be set to 0.

(3) The hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. This would be calculated by subtracting the average cost of non-domestic NIOSH-approved surgical N95 respirators purchased from the average cost of domestic NIOSH-approved surgical N95 respirators purchased. If the average cost of non-domestic NIOSH-approved surgical N95 respirators purchased is greater than the average cost of domestic NIOSH-approved surgical N95 respirators purchased, this value would be set to 0. As discussed in section X.H.8, we may consider in future rulemaking establishing a national minimum average cost for non-domestic NIOSH-approved surgical N95 respirators purchased that could be used in determining the hospital-specific unit cost differential for hospitals that only purchased domestic NIOSH-approved surgical N95 respirators or that have unusually low average costs for their non-domestic NIOSH-approved surgical N95 respirators.

Step 3—Calculate a total cost differential for the purchase of domestic NIOSH-approved surgical N95 respirators.

The next step in the proposed payment adjustment calculation is determining the total cost differential for the purchase of domestic NIOSH-approved surgical N95 respirators. This amount represents the total additional costs the hospital incurred by purchasing domestic NIOSH-approved surgical N95 respirators over purchasing non-domestic NIOSH-approved surgical N95 respirators. We propose to calculate this amount by multiplying the hospital-specific unit cost differential calculated in Step 2 by the total quantity of domestic NIOSH-approved surgical N95 respirators purchased reported in Step 1.

Step 4—Determine IPPS and OPPS share of total hospital costs.

The total cost differential calculated in Step 3 is reflective of all domestic NIOSH-approved surgical N95 respirators used throughout the hospital while treating all patients. This total cost differential needs to be disaggregated to estimate the additional costs incurred by purchasing domestic NIOSH-approved surgical N95 respirators used in treating patients receiving services paid under IPPS and OPPS, specifically. To apportion the total cost differential to the IPPS and OPPS services, we propose to use cost data already reported on the hospital cost report. We specifically propose to use the following from the Form CMS–2552–10:

(a) Total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services as reported in Worksheet C Part I line 202 column 5.

(b) Total Medicare Part A hospital inpatient costs as reported in Worksheet D–1 Part II, line 49, column 5.

(c) Total Medicare Part B hospital outpatient costs as reported in Worksheet D Part V, line 202, column 5 + column 6 + column 7.

We propose to calculate the IPPS percent share of the total cost differential (calculated in Step 3) as total Medicare Part A hospital inpatient costs (Step 4b) divided by total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services (Step 4a). We propose to calculate the OPPS percent share of the total cost differential as total Medicare Part B hospital outpatient costs (Step 4c) divided by total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services (Step 4a).

Step 5—Determine IPPS and OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.

To calculate the IPPS payment adjustment for domestic NIOSH-approved surgical N95 respirators, we propose to multiply the IPPS cost share (determined in Step 4) by the total cost differential for the purchase of domestic respirators (Step 3). To calculate the OPPS payment adjustment for domestic NIOSH-approved surgical N95 respirators, we propose to multiply the OPPS cost share (determined in Step 4) by the total cost differential for the purchase of domestic respirators (Step 3). As described previously, these calculated payment adjustments would be reconciled against interim lump-sum payments received by the hospital for this policy.

To demonstrate these calculations, in table 50 we have provided an example for a mock hospital that purchased both domestic and non-domestic NIOSH-approved surgical N95 respirators during its cost reporting period beginning on or after January 1, 2023. The example shows the additional data

[153] We note for this discussion, reference to the ''hospital'' refers to the ''hospital and hospital healthcare complex'' that completes the cost report form CMS–2552–10.

the hospital would report on its supplemental cost reporting form, the cost data pulled from other hospital cost report worksheets, and the calculations performed to determine the hospital's IPPS and OPPS payment adjustment for domestic NIOSH-approved surgical N95 respirators.

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TABLE 50: Mock N95 Supplemental Cost Reporting Form

Line Description	Data Source	Value
Line 1: Total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	150,000
Line 2: Total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	$112,500
Line 3: Total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	150,000
Line 4: Total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital .	Entered by hospital on new form.	$82,500
Line 5: Total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services	Worksheet C Part I, line 202 column 5.	$100,000,000
Line 6: Total Medicare Part A hospital inpatient costs	Worksheet D-1 Part II, line 49, column 5.	$20,000,000
Line 7: Total Medicare Part B hospital outpatient costs	Worksheet D Part V, line 202, column 5 + column 6 + column 7.	$10,000,000
Line 8: Average unit cost of domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 2 / Line 1. If line 1 is equal to 0, then set value to 0.	$0.75
Line 9: Average unit cost of non-domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 4 / Line 3. If Line 3 is equal to 0, then set value to 0.	$0.55
Line 10: Difference in average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 8 - Line 9. If value is less than 0, then set value to 0.	$0.20
Line 11: Total cost differential for purchasing domestic NIOSH-approved surgical N95 respirators.	Calculation: Line 1 * Line 10.	$30,000
Line 12: Medicare Part A hospital inpatient cost share.	Calculation: Line 6 / Line 5.	0.20
Line 13: Medicare Part B hospital outpatient cost share.	Calculation: Line 7 / Line 5.	0.10
Line 14: IPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.	Calculation: Line 11 * Line 12.	**$6,000**
Line 15: OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.	Calculation: Line 11 * Line 13.	**$3,000**

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6. Proposed Establishment of the OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators in a Budget Neutral Manner

As noted earlier, section 1833(t)(2)(E) of the Act provides that the Secretary shall establish adjustments necessary to ensure equitable payments in a budget neutral manner. In order to maintain OPPS budget neutrality, we propose to develop a spending estimate associated with this proposed policy. Specifically, this spending estimate would reflect the OPPS payment adjustment that would be made in CY 2023 for the additional resource costs of domestic NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients. The data currently available to calculate this spending estimate is limited. However, we believe the proposed methodology described next to calculate this spending estimate for CY 2023 is reasonable based on the information available.

We propose to calculate the estimated total spending associated with this policy by multiplying together estimates of the following:

(1) Estimate of the total number of NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients in CY 2023.

(2) Estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators.

(3) Estimate of the percentage of NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients in CY 2023 that are domestic.

For purposes of this estimate, we believe it is reasonable to assume that one NIOSH-approved surgical N95 respirator is used per OPPS encounter. Based on the outpatient claims volume available for ratesetting in this CY 2023 OPPS proposed rule, we have approximately 103.4 million OPPS claims. Therefore, for CY 2023, we are estimating that the total number of NIOSH-approved surgical N95 respirators (both domestic and non-domestic) used in the treatment of OPPS patients in CY 2023 is 103.4 million. Based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators is $0.20.

It is particularly challenging to estimate the percentage of domestically manufactured NIOSH-approved surgical N95 respirators that will be used in the treatment of OPPS patients in CY 2023. The OMB's Made in America Office recently conducted a data call on capacity in which several entities attested to being able to supply 3.6 billion NIOSH-approved and Berry-compliant surgical N95 respirators annually in the future if there were sufficient demand. We recognize that it may take time for this capacity to be fully reflected in hospital purchases. Therefore, although this would be sufficient capacity to supply the entire hospital industry if it were to be available and focused on this segment of the marketplace in 2023, we believe it is reasonable to assume that this will not happen instantaneously and hospitals in aggregate may in fact be able to purchase less than half of their NIOSH-approved surgical N95 respirators as domestic in 2023. Therefore, for purposes of this OPPS budget neutrality estimate, we propose to set the percentage of NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients in CY 2023 that are domestic to 40 percent, or slightly less than half.

We estimate that total CY 2023 OPPS payments associated with this policy will be $8.3 million (or 103.4 million claims × $0.20 × 40 percent). This represents approximately 0.01 percent of the OPPS, which we propose to budget neutralize through an adjustment to the OPPS conversion factor. We note that the volume of claims data available for ratesetting typically increases between the proposed and final rules, so this spending estimate may change. However, we believe this proposed methodology will best approximate CY 2023 OPPS spending associated with the proposed policy.

We recognize that this proposed approach to estimating budget neutrality under the OPPS is based on the limited data available. If finalized, we may consider refining this approach for future years, especially once data collected on cost reports for this policy is available.

7. Proposed Regulation Amendments

For the IPPS, we propose to codify this payment adjustment in the regulations by adding new paragraph (f) to § 412.113 to specify that, for cost reporting periods beginning on or after January 1, 2023, a payment adjustment is made to a hospital for the additional resource costs of domestic NIOSH-approved surgical N95 respirators. The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic NIOSH-approved surgical N95 respirators purchased during the cost reporting period as compared to other NIOSH-approved surgical N95 respirators purchased during the cost reporting period. We also propose to make conforming changes to § 412.1(a) and § 412.2(f) to reflect the proposed payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators.

For the OPPS, we propose to codify this payment adjustment in the regulations by adding a new paragraph (j) to § 419.43 to specify at new paragraph (j)(1) that, for cost reporting periods beginning on or after January 1, 2023, CMS makes a payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators. New paragraph (j)(2) would provide that the payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic NIOSH-approved surgical N95 respirators purchased during the cost reporting period as compared to other NIOSH-approved surgical N95 respirators purchased during the cost reporting period. Finally, new paragraph (j)(3) would state that CMS establishes the payment adjustment under paragraph (j)(2) in a budget neutral manner.

8. Alternatives Considered

As we gain more experience with this payment policy, if finalized, its impact on the N95 marketplace, and the data collected, we may revisit our proposed approach of payments based on the reasonable costs of each hospital as discussed in section X.H.4 and section X.H.5 of this proposed rule. As one example, we might base the payment adjustment on the national average cost differential between a domestic NIOSH-approved surgical N95 respirator and a non-domestic one as collected on the hospital cost reports, rather than use hospital specific differentials. A single national average cost differential could continue to be implemented as biweekly interim lump-sum payments reconciled at cost report settlement, or it could be implemented as a claims-based add-on payment under the IPPS and OPPS. As another example of a potential future refinement, even if we were to maintain hospital specific differentials, it may be appropriate to establish a national minimum average cost for non-domestic NIOSH-approved surgical N95 respirators for use in calculating the payment differential for a hospital that only uses domestic NIOSH-approved surgical N95 respirators or that has unusually low average costs for its non-domestic NIOSH-approved surgical respirators. We could potentially establish such a national minimum average cost using an appropriate percentile of the average unit cost of

non-domestic NIOSH-approved surgical N95 respirators across hospitals, as calculated on the cost report.

We might also revisit in future rulemaking our proposed budget neutrality approach for the OPPS payments discussed in section X.H.6 of this proposed rule, as we gain more experience with this payment policy, if finalized, and the data collected.

We received several comments on the FY 2023 IPPS/LTCH PPS proposed rule requesting these payment adjustments be expanded to include other forms of PPE such as gowns and gloves. Therefore, as we gain more experience with this payment policy, if finalized, we might also consider in future rulemaking expanding this policy to include other forms of PPE that are critical for responding to a public health emergency, including but not limited to elastomeric respirators, surgical/procedural masks, gloves, and medical gowns.

I. Proposal To Exempt Rural Sole Community Hospitals From the Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of the clinic visit service furnished in excepted off-campus provider-based departments (PBDs) by removing the payment differential that drives the site-of-service decision and, as a result, unnecessarily increases service volume in this care setting as compared to the physician's office setting. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and rationale for the volume control method we adopted beginning in CY 2019. Below we discuss the specific policy we finalized in the CY 2019 OPPS/ASC final rule with comment period and its full application under the OPPS beginning in CY 2020.

1. Implementation of a Method To Control Unnecessary Increases in the Volume of Certain Clinic Visit Services

For the CY 2019 OPPS, under our authority at section 1833(t)(2)(F) of the Act, we applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS-equivalent rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). The PFS-equivalent rate, however, was not immediately applied in full. Instead, we phased in the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted off-campus PBD setting over two years. For CY 2019, the payment reduction was transitioned by applying 50 percent of the total reduction in payment that would have applied if these departments (departments that bill the modifier ''PO'' on claim lines) were paid the PFS-equivalent rate for the clinic visit service. The PFS-equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). Consequently, these departments were paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30-percent payment reduction that was applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second and final year of the 2-year phase-in, we stated that we would apply the total reduction in payment that would be applied if these departments (departments that bill the modifier ''PO'' on claim lines) were paid the site-specific PFS-equivalent rate for the clinic visit service described by HCPCS code G0463. The PFS-equivalent rate for CY 2020 was 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate) for CY 2020. Under this policy, departments were paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2020) for the clinic visit service in CY 2020. The fully phased-in policy has been in effect since CY 2020.

In addition, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), for CY 2019 and subsequent years, this policy has been implemented in a non-budget neutral manner. To effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply increase other expenditures that are unnecessary within the OPPS, we explained that we believed the method must be adopted in a non-budget neutral manner in accordance with the OPPS statute. The impact of this policy is further described in section X of this proposed rule.

We note that this policy was previously litigated. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. The appellees petitioned the United States Supreme Court for a writ of certiorari. On June 29, 2021, the Supreme Court denied the petition.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37143), we sought public comment on whether there should be exceptions from this policy for rural providers, such as those providers that are at risk of hospital closure or those providers that are rural sole community hospitals (SCHs). Commenters to the CY 2019 OPPS/ASC proposed rule expressed concern that this policy proposal would disproportionately affect safety net hospitals and rural providers (83 FR 59013). Numerous commenters representing a rural SCH and beneficiaries in the State of Washington expressed concern about the impact the proposal would have on their rural SCH. Several commenters also requested that both urban and rural SCHs, rural referral centers (RRCs), and Medicare-dependent hospitals be exempted from this policy.

At the time we responded that we shared the commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. We stated that we believed that implementing our policy with a 2-year phase-in would help to mitigate the immediate impact on rural hospitals (83 FR 59013). We noted that we might revisit this policy to consider potential exemptions in the CY 2020 OPPS rulemaking.

In CY 2020 OPPS/ASC final rule with comment period (84 FR 61367), we again discussed commenters' continued concerns about this policy's impact on rural providers and safety net health systems. While acknowledging the validity of these concerns, we emphasized our belief that a phased-in implementation would help mitigate the impact rural hospitals might otherwise face. We reiterated that we would continue to monitor trends for any access to care issues and would potentially revisit this policy in future rulemaking.

2. Proposed Exemption for Rural Sole Community Hospitals From the Method To Control Unnecessary Increases in the Volume of Clinic Visits Furnished Beginning in CY 2023

Since the volume control method was fully phased in by the CY 2020 OPPS/

ASC final rule with comment period (84 FR 61142), we have continued to assess how this policy has been implemented, as it affects both the Medicare program itself and the beneficiaries it serves. This policy was designed to address unnecessary increases in the volume of clinic visit services furnished in excepted off-campus PBDs. While we believe that the method we adopted to control this growth is appropriate, we are continuing to examine whether all excepted off-campus PBDs should be subject to the site-specific PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463. In the CY 2019 OPPS/ASC proposed rule (83 FR 37142), we explained our position that shifts in the sites of service are unnecessary if the beneficiary can safely receive the same service in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. We described this as beneficiaries moving from (lower cost) physician offices to (higher cost) HOPDs because of the higher payment rate available in the HOPD. In these cases, we maintain that to the extent similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another as doing so results in service volume increases that we believe are unnecessary. We continue to believe the difference in payment for these services is a significant factor in the shift in services from the physician's office setting to the hospital outpatient department for many hospital types, which unnecessarily increases hospital outpatient department volume and Medicare program and beneficiary expenditures. Nonetheless, we recognize that the volume of clinic visits furnished in off-campus PBDs of certain hospital types may primarily be driven by factors other than higher payment, such as service shifts from the inpatient hospital to outpatient hospital setting and access issues. As explained further below, we propose to exempt excepted off-campus PBDs of rural SCHs from our volume control method policy because we believe the volume of the clinic visit service in PBDs of these hospitals is driven by factors other than the payment differential for this service. We propose to pay the full OPPS payment rate, rather than the PFS-equivalent rate under our volume control method, when the clinic visit is furnished in these departments.

a. Special Payment Treatment for Rural SCHs

Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to ensure access to high quality care for beneficiaries in rural areas. CMS administers five rural hospital payment designations in which rural or isolated hospitals that meet specified eligibility criteria receive higher reimbursement for hospital services than they otherwise would receive under Medicare's standard payment methodologies. A rural hospital may qualify as a Critical Access Hospital,[154] Sole Community Hospital (SCH),[155] or Medicare Dependent Hospital [156]—each of which has different eligibility criteria and payment methodologies. With the exception of Critical Access Hospitals, rural hospitals may also qualify as Low Volume Hospitals [157] and Rural Referral Centers (RRCs),[158] which qualify eligible hospitals for additional payments or exemptions. Not all rural or isolated hospitals receive special payment treatment under the OPPS. For instance, CAHs are not paid under the OPPS and are reimbursed at 101 percent of reasonable costs for outpatient services. PBDs of CAHs are not subject to Section 603 of the Bipartisan Budget Act of 2015.

Rural SCHs are a hospital type that has received special payment treatment under the OPPS to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy. This policy was adopted under section 1833(t)(13)(B) of the Act, which required the Secretary by January 1, 2006 to provide for an appropriate adjustment under paragraph (t)(2)(E) to reflect the higher costs of hospitals in rural areas if the Secretary determined, pursuant to a study required by section 1833(t)(13)(A), that the costs to rural hospitals by APC exceeded those costs for hospitals in urban areas. Our analysis revealed that rural SCHs had significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. As discussed in Section II.E of this proposed rule, for CY 2023 we propose to continue the current policy of utilizing a 7.1 percent payment adjustment for rural SCHs.

Rural SCHs have also been excluded from our policy to adjust payment for drugs and biologicals acquired under the 340B program. When we proposed to adjust payments for 340B drugs in the CY 2018 OPPS/ASC proposed rule (82 FR 33635), we sought public comment on whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals). Commenters noted that rural 340B covered entity hospitals depend on the drug discounts they receive through the 340B Program to provide access to expensive, necessary care such as labor and delivery and oncology infusions (82 FR 59365).

Commenters expressed that even with 340B discounts, rural hospitals like rural SCHs are financially threatened. They noted that rural hospitals are typically located in lower income economic areas and would not be able to absorb the proposed reduction in payment for 340B-purchased drugs. Moreover, commenters suggested that the proposal would disproportionately affect rural hospitals compared to urban hospitals and requested that CMS exempt hospitals with an RRC or SCH designation from the 340B drug payment policy. The commenters asserted that RRCs and SCHs are rural safety-net hospitals that provide localized care for Medicare beneficiaries and also serve as ''economic engines'' for many rural communities. Taking into consideration these comments, for CY 2018 we finalized a policy to exclude rural SCHs from our 340B drug payment policy and have continued to do so in CYs 2019 through 2022.

b. Utilization of the Clinic Visit Service in Off-Campus Provider-Based Departments of Rural SCHs

In the CY 2019 OPPS/ASC final rule with comment period in which we adopted the volume control method policy for certain clinic visits, we said that to the extent there are lower-cost sites of service available, beneficiaries and the physicians treating them should be able to choose the appropriate care setting and not be encouraged to receive or provide care in settings for which payment rates are higher solely for financial reasons (83 FR 37139).

[154] 42 CFR 485.601–647.

[155] 42 CFR 412.92.

[156] 42 CFR 412.108.

[157] 42 CFR 412.101.

[158] 42 CFR 412.96.

However, many rural providers, and rural SCHs in particular, are often the only source of care in their communities,[159] which means beneficiaries and providers are not merely choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas further drives utilization to off-campus PBDs in areas where rural SCHs are located.

Rural areas often experience lower availability of health care professionals and hospitals than urban areas.[160] Access to outpatient services, particularly in rural areas, is vital to keeping beneficiaries healthy and out of the hospital because beneficiaries in rural settings face unique challenges that impact their health. Compared to their urban counterparts, rural residents generally are older and poorer.[161] Rural areas are also disproportionally affected by declining population rates and decreasing employment rates.[162] We have targeted rural SCHs with their add-on payment and exemption from the 340B payment reductions in an effort to ensure that these providers with demonstrated additional resource costs remain open to serve the beneficiaries who rely on them for their care.

We believe that exempting rural Sole Community Hospitals (rural SCHs) from payment of the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines) would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at rates comparable to those paid at on-campus departments. Exempting rural SCHs would also target payment of the full OPPS rate for the clinic visit service to off-campus PBDs of these hospitals, the majority of which are located in Medically Underserved Areas (MUAs) as defined by the Health Resources and Services Administration. Our proposal also aligns with the special payment treatment rural SCHs receive under the OPPS.

Accordingly, for CY 2023, we propose that excepted off-campus PBDs (departments that bill the modifier ''PO'' on claim lines) of rural SCHs, as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, would be exempt from our volume control method of paying the PFS-equivalent rate for the clinic visit service, as described by HCPCS code G0463. Additionally, we are soliciting comments on whether it would be appropriate to exempt other rural hospitals, such as those with under 100 beds, from our volume control method of paying the PFS-equivalent rate for the clinic visit service.

In CY 2023, for a Medicare beneficiary who receives a clinic visit service in a non-excepted off-campus PBD of a rural SCH, the standard unadjusted Medicare OPPS proposed payment would be approximately $131, with an approximate average copayment of $26. The proposed PFS-equivalent rate for a clinic visit would be approximately $52, with an approximate average copayment of $10. Under this proposal, an excepted off-campus PBD of a rural SCH would continue to bill HCPCS code G0463 with the ''PO'' modifier in CY 2023, but the payment rate for services described by HCPCS code G0463 when billed with modifier ''PO'' would now be the full OPPS payment rate. This would cost beneficiaries an average of an additional $16 per visit.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we implemented the volume control method in a non-budget neutral manner consistent with the OPPS statute. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply increase other expenditures that are unnecessary within the OPPS, we stated that the volume control method in general would be implemented in a non-budget neutral manner. Here, we propose to simply remove the effects of this volume control method for one type of provider (rural SCHs), which is only a subset of the providers currently affected by our policy, and thus propose this exception would not increase OPPS spending overall as compared to OPPS spending with no volume control method whatsoever. We estimate that this exemption would increase OPPS spending by approximately $75 million in CY 2023 compared to spending if we did not implement this exemption to the volume control method. The impact associated with this policy is further described in section XXVI of this proposed rule.

XI. Proposed CY 2023 OPPS Payment Status and Comment Indicators

A. Proposed CY 2023 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 whether particular OPPS policies apply to the code.

For CY 2023, we propose to revise the definition of status indicator ''A'' to include unclassified drugs and biologicals that are reportable under HCPCS code C9399. When HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's average wholesale price (AWP) using the Red Book or an equivalent recognized compendium, and processes the claim for payment. The payment at 95 percent of AWP is made under the OPPS.

In addition, we propose to revise the definition of status indicator ''F'' by removing hepatitis B vaccines. Hepatitis B vaccines should not be subject to deductible and coinsurance similar to other preventive vaccines, but services that are currently listed under the definition of status indicator ''F'' are subject to deductible and coinsurance. We also propose to revise the definition of status indicator ''L'' in order to add hepatitis B vaccines to the list of other preventive vaccines that are not subject to deductible and coinsurance.

The complete list of proposed CY 2023 payment status indicators and their definitions is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

We are requesting public comments on the proposed definitions of the OPPS payment status indicators for 2023.

The proposed CY 2023 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 website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

[159] *https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf.*

[160] *https://www.gao.gov/assets/gao-21-93.pdf.*

[161] *https://www.gao.gov/assets/gao-21-93.pdf.*

[162] *https://www.gao.gov/assets/gao-21-93.pdf.*

B. Proposed CY 2023 Comment Indicator Definitions

In this proposed rule, we propose to use four comment indicators for the CY 2023 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2022 and we propose to continue their use in CY 2023. The proposed CY 2023 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2023 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We believe that the existing CY 2022 definitions of the OPPS comment indicators continue to be appropriate for CY 2023. Therefore, we propose to use those definitions without modification for CY 2023.

We are requesting public comments on our proposed definitions of the OPPS comment indicators for 2023.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2022 report.

A. Proposed OPPS Payment Rates Update

The March 2022 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress update Medicare OPPS payment rates by the amount specified in current law. We refer readers to the March 2022 report for a complete discussion of this recommendation.[163] We appreciate MedPAC's recommendation and, as discussed further in Section II.A.4 of this proposed rule, we propose to increase the OPPS payment rates by the amount specified in current law. Comments received from MedPAC for other OPPS policies are discussed in the applicable sections of this proposed rule.

B. Proposed ASC Conversion Factor Update

In the March 2022 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased prior to the effects of COVID–19 PHE in CY 2020, and ASC access to capital has been adequate.[164] As a result, MedPAC stated that payments to ASCs are adequate and recommended that, in the absence of cost report data, no payment update should be applied for CY 2023 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the productivity-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in section XIII.G of this proposed rule, we propose to apply a 2.7 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the proposed CY 2023 ASC payment amounts. The proposed CY 2023 ASC conversion factor for ASCs meeting quality reporting requirements and the proposed hospital market basket update factor are discussed in section XIII of this proposed rule.

C. Proposed ASC Cost Data

In the March 2022 MedPAC ''Report to the Congress: Medicare Payment Policy,'' 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, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program but should make cost reporting a condition of ASC participation in the Medicare program.[165]

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we are not proposing any cost reporting requirements for ASCs in this CY 2023 OPPS/ASC proposed rule, we continue to seek public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing an ASC-specific market basket index for updating payment rates under the ASC payment system.

[163] Medicare Payment Advisory Committee. March 2022 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, pp.65–66. Available at: *http://www.medpac.gov*.

[164] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.161–162. Available at: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_entirereport_sec.pdf*.

[165] Medicare Payment Advisory Committee. March 2022 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.162. Available at: *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf*.

XIII. 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 to 2022 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; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410, 85 FR 86121 through 86179, and 86 FR 63761 through 63815 respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under §§ 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, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15.

Since the implementation of the ASC prospective payment system, we have historically 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.

As we noted in the August 7, 2007 ASC final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, ''surgery-like'' procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. In that final rule, we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the general standards established in previous years for addition to the ASC CPL. These criteria included that a procedure is not expected to pose a significant risk to beneficiary safety when performed in an ASC, that standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and that the procedure is separately paid under the OPPS.

In CY 2021, we revised the definition of covered surgical procedures to only surgical procedures specified by the Secretary that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15 (85 FR 86153). However, in the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to reinstate the general standards and exclusion criteria in place prior to CY 2021 (86 FR 63779) and revised the language in the regulation text at § 416.166 accordingly.

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we 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; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. 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 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 paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the AMA and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC

final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

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, 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.

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes Category I, II, III, MAAA, and PLA CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and 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, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 ASC final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we referred 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 proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in this proposed rule or whether we will be soliciting public comments in the CY 2023 OPPS/ASC final rule with comment period.

2. April 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2022 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2022 ASC quarterly update (Transmittal 11303, dated March 24, 2022, CR 12679), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 51 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2022) lists the new Level II HCPCS codes that were implemented April 1, 2022. The proposed comment indicators (CI), payment indicators (PI), and payment rates for these April codes can be found in Addendum BB to this proposed rule. The list of proposed ASC PIs and corresponding definitions can be found in Addendum DD1 to this proposed rule. The new codes that are effective April 1, 2022, are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator assignment and that comments will be accepted on the interim assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that the following ASC addenda are available via the internet on the CMS website:

- ASC Addendum AA: Proposed ASC Covered Surgical Procedures for CY 2023 (Including Surgical Procedures for Which Payment is Packaged)
- ASC Addendum BB: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2023 (Including Ancillary Services for Which Payment is Packaged)
- ASC Addendum DD1: Proposed ASC Payment Indicators (PI) for CY 2023, and
- ASC Addendum DD2: Proposed ASC Comment Indicators (CI) for CY 2023

We are inviting public comments on these proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2022 through the quarterly update CRs, as listed in Table 51 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2022). We propose to finalize the payment indicators in the CY 2023 OPPS/ASC final rule with comment period.

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TABLE 51: NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE APRIL 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
A2011	Supra sdrm, per square centimeter
A2012	Suprathel, per square centimeter
A2013	Innovamatrix fs, per square centimeter
A4100	Skin substitute, fda cleared as a device, not otherwise specified
C9090	Injection, plasminogen, human-tvmh, 1 mg
C9091	Injection, sirolimus protein-bound particles, 1 mg
C9092	Injection, triamcinolone acetonide, suprachoroidal, 1 mg
C9093	Injection, ranibizumab, via intravitreal implant, 0.1 mg
C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0491	Injection, anifrolumab-fnia, 1 mg
J9071	Injection, cyclophosphamide, (auromedics), 5 mg
J9273	Injection, tisotumab vedotin-tftv, 1 mg
J9359	Injection, loncastuximab tesirine-lpyl, 0.1 mg
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	Amniobind, per square centimeter
Q4256	Mlg-complete, per square centimeter
Q4257	Relese, per square centimeter
Q4258	Enverse, per square centimeter

3. July 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2022 ASC quarterly update (Transmittal 11472, Change Request 12773, dated June 23, 2022), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 52 (New Level II HCPCS Codes for Ancillary Services Effective July 1, 2022) lists the new HCPCS codes that are effective July 1, 2022. The proposed comment indicators, payment indicators, and payment rates for the codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of proposed ASC PIs and corresponding definitions can be found in Addendum DD1 to this proposed rule. In addition, these new codes that are effective July 1, 2022 are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on the interim assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 52: NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie
C9094	Inj, sutimlimab-jome, 10 mg
C9095	Inj, tebentafusp-tebn, 1 mcg
C9096	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram
C9097	Inj, faricimab-svoa, 0.1 mg
C9098	ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
J0739	Injection, cabotegravir, 1 mg
J1306	Injection, inclisiran, 1 mg
J1551	Injection, immune globulin (cutaquig), 100 mg
J2356	Injection, tezepelumab-ekko, 1 mg
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2998	Injection, plasminogen, human-tvmh, 1 mg
J3299	Injection, triamcinolone acetonide (xipere), 1 mg
J9331	Injection, sirolimus protein-bound particles, 1 mg
J9332	Injection, efgartigimod alfa-fcab, 2mg
Q4259	Celera dual layer or celera dual membrane, per square centimeter
Q4260	Signature apatch, per square centimeter
Q4261	Tag, per square centimeter

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Furthermore, through the July 2022 quarterly update CR, we added three new Category III CPT codes to the list of ASC covered ancillary services, effective July 1, 2022. These codes are listed in Table 53 (New Category III CPT Codes for Covered Ancillary Services Effective July 1, 2022). The CY 2023 proposed payment indicators, proposed comment indicators, and proposed payment rates for these new Category III CPT codes can be found in Addendum BB to this proposed rule. As noted above, the list of payment indicators and comment indicators used under the ASC can be found in Addendum DD1 and DD2, respectively, of this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 53: NEW CATEGORY III CPT CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score

We are inviting public comments on the proposed payment indicators for the new CPT and Level II HCPCS codes newly recognized as ASC covered surgical procedures for covered ancillary services effective April 1, 2022, and July 1, 2022, through the quarterly update CRs, as listed in Tables 51, 52, and 53. We propose to finalize the payment indicators in the CY 2023 OPPS/ASC final rule with comment period.

4. October 2022 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2023 OPPS/ASC Final Rule With Comment Period

For CY 2023, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2022, would be flagged with comment indicator ''NI'' in Addendum BB in the CY 2023 OPPS/ASC final rule with comment period to indicate that we have assigned the codes interim ASC payment indicators for CY 2023. We will invite public comments in the CY 2023 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2024 OPPS/ASC final rule with comment period.

5. January 2023 HCPCS Codes

a. Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2023 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that, unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the C and G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2023 OPPS/ASC final rule with comment period, January 2023 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2023, we will propose to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2023, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2023 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2024 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the CY 2023 ASC update, we received the CPT codes that will be effective January 1, 2023, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum BB to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We will accept comments and finalize the payment indicators in the CY 2023 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we include the 5-digit placeholder codes and their long descriptors for the new CY 2023 CPT codes in Addendum O to this proposed rule so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled ''CY 2023 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' We intend to include the final CPT code numbers the CY 2023 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2023 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2023. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2023 OPPS/ASC final rule with comment period. The codes, along with their proposed payment indicators, and proposed comment indicators, are listed in ASC Addendum AA and BB. The definitions for the proposed payment indicators and comment indicators can be found in ASC Addendum DD1 and DD2, respectively. All the ASC proposed rule payment files, including ASC Addenda

AA, BB, DD1, and DD2, are available via the internet on the CMS website.

Finally, in Table 54, 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 ASC.

TABLE 54: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2022	HCPCS (CPT and Level II codes)	April 1, 2022	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
July 2022	HCPCS (CPT and Level II codes)	July 1, 2022	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
October 2022	HCPCS (CPT and Level II codes)	October 1, 2022	CY 2023 OPPS/ASC final rule with comment period	CY 2024 OPPS/ASC final rule with comment period
January 2023	CPT Codes	January 1, 2023	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2023	CY 2023 OPPS/ASC final rule with comment period	CY 2024 OPPS/ASC final rule with comment period

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 Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished 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 CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule with 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 ASC standard ratesetting 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 ASC CPL to include all 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 2023 to Covered Surgical Procedures Designated as Office-Based

In developing this CY 2023 OPPS/ASC 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 (described in detail in section XIII.C.1.d. of this final rule with comment period), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2021 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2022 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

In our CY 2022 OPPS/ASC final rule with comment period (86 FR 63770), we discussed that we, historically, review the most recent claims volume and utilization data and clinical characteristics for all covered surgical procedures that were assigned a payment indicator of ''G2'' for CY 2021. For the CY 2022 OPPS/ASC final rule with comment period, the most recent claims volume and utilization data was CY 2020 claims. However, given our concerns with the use of CY 2020 claims data as a result of the COVID–19 PHE as further discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), we adopted a policy to not review CY 2020 claims data and did not assign permanent office-based designations to covered surgical procedures that were assigned a payment indicator of ''G2'' in CY 2021 (86 FR 63770 through 63771).

As discussed further in section X.B of this proposed rule, in our review of the CY 2021 outpatient claims available for ratesetting for this CY 2023 OPPS proposed rule, we observed that many outpatient service volumes have partially returned to their pre-PHE levels and it is reasonable to assume that there will continue to be some effects of the COVID–19 PHE on the outpatient claims that we use for OPPS ratesetting. As a result, we propose to use the CY 2021 claims for CY 2023 OPPS ratesetting. Similarly, for this proposed rule, we propose to resume our historical practice and review the most recent claims and utilization data, in this case data from CY 2021 claims, for determining office-based assignments under the ASC payment system.

Our review of the CY 2021 volume and utilization data of covered surgical procedures currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of 6 surgical procedures that we believe meet the criteria for designation as permanently 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 propose to permanently designate as office-based for CY 2023 are listed in Table 55.

TABLE 55: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2023

CY 2023 CPT/HCPCS Code	CY 2022 Long Descriptor	CY 2022 ASC Payment Indicator	Proposed CY 2023 ASC Payment Indicator*
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy	G2	P3*
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	G2	P2*
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	G2	R2*
21198	Osteotomy, mandible, segmental;	G2	R2*
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral	G2	R2*
40830	Closure of laceration, vestibule of mouth; 2.5 cm or less	G2	R2*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2023 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2023 PFS proposed rule.

We also reviewed CY 2021 volume and utilization data for 8 surgical procedures designated as temporarily office-based in the CY 2022 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2'' as shown in Table 56. For all 8 surgical procedures, there were fewer than 50 claims or no claims in our data. Therefore, we propose to continue to designate these procedures, shown in Table 56, as temporarily office-based for CY 2023. The procedures for which the proposed office-based designation for CY 2023 is temporary are indicated by an asterisk in Addendum AA to this proposed rule (which is available via the internet on the CMS website).

TABLE 56: PROPOSED CY 2023 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2022 OPPS/ASC FINAL RULE

CY 2022 CPT/HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator	Proposed CY 2023 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2023 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2023 PFS proposed rule.

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As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures

would be permanently assigned to the list of office-based procedures. In the absence of claims data, we stated we would use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period. For CY 2023, there are no new CY 2023 CPT codes for ASC covered surgical procedures that have been temporarily assigned office-based.

b. Device-Intensive ASC Covered Surgical Procedures

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2023

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2 of CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

As discussed in more detail in section XIII.D.1.c of this proposed rule, we propose to create a special payment policy under the ASC payment system whereby we would add 52 new C codes to the ASC CPL to provide a special payment for code combinations eligible for complexity adjustments under the OPPS. These code combinations reflect separately payable primary procedures on the ASC CPL as well as add-on procedures that are packaged with an ASC payment indicator of ''N1'' (Packaged service/item; no separate payment made.). Under our proposal, the C code would retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. The device offset percentage for a C code would be established by dividing the device portion of the primary procedure by the OPPS complexity-adjusted APC payment rate based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive status are a component of a C code.

Based on our existing criteria as well as our proposal to add to the ASC CPL new C codes that reflect code combinations eligible for complexity adjustments under the OPPS, for CY 2023, we propose to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology. For CY 2023, where CY 2021 claims data are available, the device-intensive payment methodology relies on the proposed device-offset percentages of each device-intensive procedure using the CY 2021 OPPS claims and cost report data available for this proposed rule.

The ASC covered surgical procedures that we propose to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2023, are assigned

payment indicator ''J8'' and are included in ASC Addendum AA to this proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, the proposed CY 2023 ASC payment rate are also included in Addendum AA to this proposed rule (which is available via the internet on the CMS website). We are soliciting public comments on our proposal to assign device-intensive status to 11 of the new C codes that we propose to add to the ASC CPL as well as our methodology for determining the device portion for such procedures.

c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced 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.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit 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.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert 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 or insert 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.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit 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 will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure 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 have the option of either: (1) submitting the claim for the device-intensive 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 or insertion 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 device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit 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 device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we proposed to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years. Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit 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 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 device, ASCs have the option of either: (1) submitting the claim for the device intensive 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 or insertion 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 device. Beneficiary coinsurance would be based on the reduced payment amount.

We are not proposing any changes to our policies related to no/cost full credit or partial credit devices for CY 2023.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders.

Under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary 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.

Section 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 and CY 2022 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805).

1. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2023

Our current policy, which includes consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to the ASC CPL, is intended to ensure that surgical procedures added to the ASC CPL can be performed safely in the ASC setting on the typical Medicare beneficiary. For CY 2023, we conducted a review of procedures that currently are paid under the OPPS and not included on the ASC CPL. We also assessed procedures against our regulatory safety criteria at § 416.166. Based upon this review, we propose to update the ASC CPL by adding one lymphatic procedure to the list for CY 2023, as shown in Table 57 below.

After reviewing the clinical characteristics of this procedure, as well as consulting with stakeholders and multiple clinical advisors, we determined that this procedure is separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. This procedure does not result in extensive blood loss, require major or prolonged invasion of body cavities, or directly involve major blood vessels. We believe this procedure may be appropriately performed in an ASC on a typical Medicare beneficiary. Therefore, we propose to include this procedure on the ASC CPL for CY 2023.

TABLE 57: CY 2023 PROPOSED SURGICAL PROCEDURES FOR THE ASC CPL

CY 2023 CPT/HCPCS Code	CY 2023 Long Descriptor
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)

We continue to focus on maximizing patient access to care by adding procedures to the ASC CPL when appropriate. While expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years. We encourage stakeholders to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet our criteria and can be safely performed on the typical Medicare beneficiary in the ASC setting.

Proposed Name Change and Start Date of Nominations Process

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to add a nominations process for adding surgical procedures to the ASC CPL at § 416.166(d), (86 FR 63782) which we titled ''Nominations.'' As we have discussed in previous rulemaking, this process is simply an opportunity outside of the existing public comment period process for interested parties to submit recommendations before the proposed rule period so CMS can consider the suggestions as we develop the proposed rule. We believe this process enhances transparency and allows interested parties an additional opportunity to provide input for the ASC CPL.

However, the nominations process is not the only way for interested parties to make recommendations to CMS for adding surgical procedures to the ASC CPL. We emphasize that interested parties have been able, and may

continue, to suggest surgical procedures they believe should be added to the ASC CPL during the public comment period following the proposed rule. That process remains unchanged. When interested parties submit procedure recommendations for the ASC CPL through the public comment process, CMS will consider them for the final rule with comment period. We understand, however, that the terminology we used in the CY 2022 OPPS/ASC final rule with comment period and codified at § 416.166(d)—''Nominations''—may have led to some confusion that this process is the primary or only pathway for interested parties to suggest procedures to be added to the ASC CPL. Therefore, we propose to change the name of the process finalized last year in the CY 2022 OPPS/ASC final rule with comment period from ''Nominations'' to the ''Pre-Proposed Rule CPL Recommendation Process.'' Where the current name of the process may suggest a formality or limitation that we did not intend—one that implies the nominations process is the preferred, primary, or only means by which interested parties may submit recommendations—we believe this proposed new name would not.

In addition, we are currently working on developing the technological infrastructure and Paperwork Reduction Act (PRA) package for the recommendations process. Because we were unable to complete the infrastructure development and PRA processes (which have taken longer than we originally anticipated when we finalized the policy) in time for commenters to recommend procedures to be added to the ASC CPL prior to the CY 2023 proposed rule, we propose to revise the start date of the recommendation process in the regulatory text. We propose to change January 1, 2023, to January 1, 2024, so that the text at § 416.166(d) would specify that on or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year. We continue to welcome all procedure submissions through the public comment process, as we have in previous years.

2. Covered Ancillary Services

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2022, but will be packaged under the CY 2023 OPPS, we would also package the ancillary service under the ASC payment system for CY 2023 to maintain consistency with the OPPS. Comment indicator ''CH'', which is discussed in section XIII.G of this proposed rule, is used in Addendum BB (which is available via the internet on the CMS website) to indicate covered ancillary services for which we propose a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2023.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490).

New CPT and HCPCS codes for covered ancillary services for CY 2023 can be found in section XIII.B of this proposed rule. All ASC covered ancillary services and their proposed payment indicators for CY 2023 are also included in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

D. Proposed Update and Payment for ASC 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 described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2''. Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.1.a of this proposed rule, we update the payment amounts for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') using the most recent available MPFS and OPPS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.1.b of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device

removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is 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 ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2023

We propose to update ASC payment rates for CY 2023 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. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we propose that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We propose 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 to identify device-intensive procedures, using the methodology discussed in section XII.C.1.b of this proposed rule. Therefore, we propose to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2023 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2023 MPFS nonfacility PE RVU-based amount or the proposed CY 2023 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2022, for CY 2023, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

c. Proposed ASC Payment for Combinations of Primary and Add-On Procedures Eligible for Complexity Adjustments Under the OPPS

In this section we propose a policy to provide increased payment under the ASC payment system for combinations of certain ''J1'' service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

OPPS C–APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.b.1 of this proposed rule, we apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and add-on codes from the originating Comprehensive APC (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. A ''J1'' status indicator refers to a hospital outpatient service paid through a C–APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C–APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b of this proposed rule, in the originating C–APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. 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 that are either assigned to status indicator ''J1'' or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of ''J1'' services, or combinations of a ''J1'' service and add-on code, 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 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 C–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).

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 the primary service code reported with the add-on code is not reassigned to the next higher cost C–APC. We list the complexity adjustments for ''J1'' and add-on code combinations for CY 2022, along with all of the other final complexity adjustments, in Addendum J to the CY 2022 OPPS/ASC final rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*).

Proposed ASC Special Payment Policy for OPPS Complexity-Adjusted C–APCs

Comprehensive APCs cannot be adopted in the ASC payment system due to limitations of the ASC claims processing systems. Thus, we do not use the OPPS comprehensive services ratesetting methodology in the ASC payment system. Under the standard ratesetting methodology used for the ASC payment system, comprehensive ''J1'' claims that exist under the OPPS

are treated the same as other claims that contain separately payable procedure codes. As comprehensive APCs do not exist under the ASC payment system, there is not a process similar to the OPPS complexity adjustment policy in the ASC payment system to provide higher payment for more complex code combinations. In the ASC payment system, when multiple procedures are performed together in a single operative session, most covered surgical procedures are subject to a 50-percent reduction for the lower-paying procedure (72 FR 66830). This multiple procedure reduction gives providers additional payment when they perform multiple procedures during the same session, while still encouraging providers to provide necessary services as efficiently as possible. Add-on procedure codes are not separately payable under the ASC payment system and are always packaged into the ASC payment rate for the procedure. Unlike the multiple procedure discounting process used for other surgical procedures in the ASC payment system, providers do not receive any additional payment when they perform a primary service with an add-on code in the ASC payment system.

In previous rulemaking, we have received suggestions from commenters requesting that we explore ways to increase payment to ASCs when services corresponding to add-on codes are performed with procedures, as certain code combinations may represent increased procedure complexity or resource intensity when performed together. For example, in the CY 2022 OPPS/ASC final rule with comment period, one commenter suggested that we modify the device-intensive criteria to allow packaged procedures that trigger a complexity adjustment under the OPPS to be eligible for device-intensive status under the ASC payment system (86 FR 63775). Based on our internal data review and assessment at that time, our response to that comment noted that we did not believe any changes were warranted to our packaging policies under the ASC payment system but that we would consider it in future rulemaking.

For this CY 2023 rulemaking, we evaluated the differences in payment in the OPPS and ASC settings for code pairs that included a primary procedure and add-on codes that were eligible for complexity adjustments under the OPPS and also performed in the ASC setting. Under the ASC payment system, we identified 26 packaged procedures (payment indicator = ''N1'') that combine with 42 primary procedures, which would be C–APCs (status indicator = ''J1'') under the OPPS, to produce 52 different complexity adjustment code combinations. We generally estimate that ASC services were paid approximately 55 percent of the OPPS rate for similar services in CY 2021. When we compared the OPPS complexity-adjusted payment rate of these primary procedure and add-on code combinations to the ASC payment rate for the same code combinations, we found that the average rate of ASC payment as a percent of OPPS payment for these code combinations was 25 to 35 percent, which is significantly lower than 55 percent.

We recognize that this payment differential between the C–APC-assigned code combinations eligible for complexity adjustments under the OPPS and the same code combinations under the ASC payment system could potentially create financial disincentives for providers to offer these services in the ASC setting, which could potentially result in Medicare beneficiaries encountering difficulties accessing these combinations of services in ASC settings. As noted above, our current policy does not include additional payment for services corresponding to add-on codes, unlike our payment policy for multiple surgical procedures performed together, for which we provide additional payment under the multiple procedure reduction. However, these primary procedure and add-on code combinations that would be eligible for a complexity adjustment under the OPPS still represent more complex and costly versions of the service, and we believe that providers not receiving additional payment under the ASC payment system to compensate for that increased complexity could lead to providers not being able to provide these services in the ASC setting which could result in barriers to beneficiary access.

In order to address this issue, we propose a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code combinations at a higher payment rate to reflect that the code combination is a more complex and costlier version of the procedure performed, similar to the way in which the OPPS APC complexity adjustment is applied to certain paired code combinations that exhibit materially greater resource requirements than the primary service. We propose to add new § 416.172(h) to codify this policy.

We propose that combinations of a primary procedure code and add-on codes that are eligible for a complexity adjustment under the OPPS (as listed in OPPS Addendum J) would be eligible for this proposed payment policy in the ASC setting. Specifically, we propose that the ASC payment system code combinations eligible for additional payment under this proposed policy would consist of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC Covered Procedures List (CPL) and ancillary services list. Add-on codes are assigned payment indicator ''N1'' (Packaged service/item; no separate payment made), as listed in the ASC addenda.

Regarding eligibility for this special payment policy, we propose that we would assign each eligible code combination a new C code that describes the primary and the add-on procedure(s) performed. C codes are unique temporary codes and are only valid for claims for HOPD and ASC services and procedures. Under our proposal, we would add these C codes to the ASC CPL and the ancillary services list, and when ASCs bill this C code, they would receive a higher payment rate that reflects that the code combination is a more complex and costlier version of the procedure performed. We anticipate that the C codes eligible for this proposed payment policy would change slightly each year, as the complexity adjustment assignments change under the OPPS and we expect we would add new C codes each year accordingly. We propose 52 such new C codes to add to the ASC CPL. These proposed C codes for CY 2023 can be found in the ASC addenda. We propose to add new § 416.172(h)(1), titled Eligibility, to codify this policy.

We propose the following payment methodology for this proposed policy, which we would reflect in new § 416.172(h)(2), titled Calculation of Payment. We propose that the C codes would be subject to all ASC payment policies, including the standard ASC payment system ratesetting methodology, meaning, they would be treated the same way as other procedure codes in the ASC setting. For example, the multiple procedure discounting rules would apply to the primary procedure in cases where the services corresponding to the C code are performed with another separately payable covered surgical procedure in the ASC setting. We propose to use the OPPS complexity-adjusted C–APC rate to determine the ASC payment rate for qualifying code combinations, similar to how we use OPPS APC relative weights in the standard ASC payment system ratesetting methodology. Under the ASC

payment system, we use the OPPS APC relative payment weights to update the ASC relative payment weights for covered surgical procedures since ASCs do not submit cost reports. We then scale those ASC relative weights for the ASC payment system to ensure budget neutrality. To calculate the ASC payment rates for most ASC covered surgical procedures, we multiply the ASC conversion factor by the ASC relative payment weight. A more detailed discussion of this methodology is provided in the in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831).

For this proposal, we propose to use the OPPS complexity-adjusted C–APC rate for each corresponding code combination to calculate the OPPS relative weight for each corresponding ASC payment system C code, which we believe would appropriately reflect the complexity and resource intensity of these ASC procedures being performed together. For C codes that are not assigned device-intensive status (discussed below), we would multiply the OPPS relative weight by the ASC budget neutrality adjustment (or ASC weight scalar) to determine the ASC relative weight. We would then multiply the ASC relative weight by the ASC conversion factor to determine the ASC payment rate for each C code. In short, we would apply the standard ASC ratesetting process to the C codes. We propose to add new § 416.172(h)(2)(i) to codify this policy.

As discussed in section XIII.C.1.b of this proposed rule, certain C codes under our proposed policy may include a primary procedure that also qualifies for device-intensive status under the ASC payment system. For primary procedures assigned device-intensive status and that are a component of a C code created under this proposal, we believe it would be appropriate for the C code to retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. For example, if the primary procedure had a device offset percentage of 31 percent (a proposed device offset percentage of greater than 30 percent would be needed to qualify for device-intensive status) and a device portion (or device offset amount) of $3,000, C codes that included this primary procedure would be assigned device-intensive status and a device portion of $3,000 to be held constant with the OPPS. We would apply our standard ASC payment system ratesetting methodology to the non-device portion of the OPPS complexity-adjusted APC rate of the C codes; that is, we would apply the ASC budget neutrality adjustment and ASC conversion factor. We believe assigning device-intensive status and transferring the device portion from the primary procedure's ASC payment rate to the C code's ASC payment rate calculation is consistent with our treatment of device costs and determining device-intensive status under the ASC payment system and is an appropriate methodology for determining the ASC payment rate. The non-device portion would be the difference between the device portion of the primary procedure and the OPPS complexity-adjusted APC payment rate for the C code based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive status are a component of a C code. As is the case for all device-intensive procedures, we would apply the ASC standard ratesetting methodology to the OPPS relative weights of the non-device portion for any C code eligible for payment under this proposal. That is, we would multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate. We propose to add new § 416.172(h)(2)(ii) to codify this policy.

In order to include these C codes in the budget neutrality calculations for the ASC payment system, we propose to estimate the potential utilization for these C codes. We do not have claims data for packaged codes in the ASC setting because ASCs do not report packaged codes under the ASC payment system. Therefore, we propose to estimate CY 2023 ASC utilization based upon how often these combinations are performed in the HOPD setting. Specifically, we would use the ratio of the primary procedure volume to add-on procedure volume from CY 2021 OPPS claims and apply that ratio against ASC primary procedure utilization to estimate the increased spending as a result of our proposal for budget neutrality purposes. We believe this method would provide a reasonable estimate of the utilization of these code combinations in the ASC setting, as it is based on the specific code combination utilization in the OPPS. We anticipate that we would continue this estimation process until we have sufficient claims data for the C codes that can be used to more accurately calculate code combination utilization in ASCs, likely for the CY 2025 rulemaking.

We welcome comments on this proposal, including comments or suggestions regarding additional approaches that we should consider for this policy.

d. Proposed Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b of this proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for this proposed rule, we propose to designate 4 brachytherapy APCs and 4 clinical APCs as Low Volume APCs under the ASC payment system. The 4 clinical APCs and 4 brachytherapy APCs shown in Table 58 meet our criteria of having fewer than 100 single claims in the claims year (CY 2021 for this proposed rule) and therefore, we propose that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. These 8 APCs were designated as Low Volume APCs in CY 2022; however, as we noted under the comprehensive ratesetting methodology section, APC 2647 (Brachytherapy, non-stranded, Gold-198), which was previously designated as a Low Volume APC for CY 2022, did

not meet our claims threshold for this proposed rule.

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TABLE 58 : COST STATISTICS FOR PROPOSED LOW VOLUME APCS STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2023

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2023 APC Cost
2632	Iodine I-125 sodium iodide	9	$141.23	$31.74	$44.35	$37.26	$44.35
2635	Brachytx, non-str, HA, P-103	26	$125.24	$34.04	$51.09	$42.77	$51.09
2636	Brachy linear, non-str, P-103	0	---*	$49.65	$53.38	$38.80	$53.38
2647	Brachytx, NS, Non-HDRIr-192	14	$144.37	$184.49	$377.65	$141.18	$377.65
5244	Level 4 Blood Product Exchanges and Related Services	0	---*	$45,068.10	$44,803.39	$42,607.70	$45,068.10
5493	Level 3 Intraocular Procedures	11	$11,224.89	$11,959.68	$11,639.45	$10,858.70	$11,959.68
5494	Level 4 Intraocular Procedures	28	$1,736.78	$3,003.25	$3,371.21	$2,901.57	$3,371.21
5495	Level 5 Intraocular Procedures	7	$13,013.71	$17,567.13	$17,798.92	$15,941.10	$17,798.92

* For this proposed rule, there are no CY 2021 claims that contain the HCPCS code assigned to APC 2636 (HCPCS code C2636) or APC 5244 (CPT code 38240) that are available for CY 2023 OPPS/ASC ratesetting.

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2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N'', ''Q1'', and ''Q2'') under the OPPS.

In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the 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 generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2023

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2023 OPPS and ASC payment rates and subsequent years' payment rates. We also propose to continue to set the CY 2023 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2023 and subsequent years' payment rates.

Covered ancillary services and their proposed payment indicators for CY 2023 are listed in Addendum BB of this proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2023. For a discussion of the PFS rates, we refer readers to the CY 2023 PFS proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

3. Proposal in Physician Fee Schedule Proposed Rule To Require HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (''the Infrastructure Act'') amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. Section III.A. of the CY 2023 Physician Fee Schedule (PFS) proposed rule includes proposals to implement section 90004 of the Infrastructure Act, including a proposal that HOPDs and ASCs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPPS or ASC payment system. Specifically, we propose in the CY 2023 PFS proposed rule that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or

single-use package drug, if any, that were discarded for dates of service during a relevant quarter for the purpose of calculating the refund amount described in section 1847A(h)(3) of the Act. The CY 2023 PFS proposed rule also proposes to require HOPDs and ASCs to use a separate modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

Because the CY 2023 PFS proposed rule proposes to codify certain billing requirements for HOPDs and ASCs, we want to ensure interested parties are aware of them and know to refer to that rule for a full description of the proposed policy. Interested parties should submit comments on this and any other proposals to implement Section 90004 of the Infrastructure Act in response to the CY 2023 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2023 PFS final rule. We note that this same notice appears in section V.A.C. of this proposed rule.

E. ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies

1. Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) Act (Pub. L. 115–271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For a detailed discussion of rulemaking on non-opioid alternatives prior to CY 2020, we refer readers to the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59345; 83 FR 58855 through 58860).

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 to 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they were furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only Exparel and Omidria met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting, and received separate payment under the ASC payment system.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63483), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS/ASC drug packaging threshold, and we finalized our proposed regulation text changes at 42 CFR 416.164(a)(4) and (b)(6), § 416.171(b)(1), and § 416.174 as proposed. We determined that four products were eligible for separate payment in the ASC setting under our final policy for CY 2022. We noted that future products, or products not discussed in that rulemaking that may be eligible for separate payment under this policy would be evaluated in future rulemaking (86 FR 63496). Table 59 lists the four drugs that met our finalized criteria established in CY 2022 and received separate payment under the ASC payment system when furnished in the ASC setting for CY 2022 as described in the CY 2022 final rule with comment period (86 FR 63496).

TABLE 59: SUMMARY OF PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2022

HCPCS Code	Long Descriptor	Final CY 2022 OPPS Status Indicator (SI)*	Final CY 2022 ASC Payment Indicator (PI)*
C9290	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	N	K2
C9089	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC Addenda BB for proposed applicable payment rates, OPPS Addenda D1 for proposed SI definitions, and ASC Addenda DD1 for proposed PI definitions. All are available via the internet on the CMS website.

2. Eligibility Criteria Technical Clarification and Proposed Regulation Text Changes Regarding Pass-Through Status and Separately Payable Status

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), we finalized a policy that non-opioid pain management drugs and biologicals that function as supplies in surgical procedures that are already paid separately, including through transitional drug pass-through status under the OPPS, are not eligible for payment under § 416.174. As we previously noted in the CY 2022 OPPS/ASC final rule with comment period, once transitional pass-through payment status expires, a drug or biological may qualify for separate payment under the ASC payment system if it meets the eligibility criteria at § 416.174 (86 FR 63489). OPPS pass-through status expires on a quarterly basis. Therefore, for products for which pass-through status has expired that qualify for separate payment under the ASC payment system as non-opioid pain management drugs and biologicals that function as surgical supplies, separate payment may begin the first day of the next calendar year quarter following pass-through expiration. For example, a drug with expiring pass-through status on June 30, 2024, may begin to receive separate payment in the ASC setting on July 1, 2024, under this proposed policy, if it meets the other relevant criteria and such separate payment is finalized in the applicable year's OPPS/ASC rulemaking.

Although we established this policy in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), we did not reflect it in regulation text. We propose now to clarify our policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at § 416.174 as a technical change. First, we propose to provide at new § 416.174(a)(3) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we propose that new § 416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174.

3. Proposed CY 2023 Qualification Evaluation for Separate Payment of Non-Opioid Pain Management Drugs and Biologicals That Function as a Surgical Supply

As noted above, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS drug packaging threshold beginning on or after January 1, 2022. For CY 2023, the OPPS drug packaging threshold is proposed to be $135. For more information on the drug packaging threshold, see section V.B.1.a of this proposed rule.

The following sections include the non-opioid alternatives of which we are aware and our evaluations of whether these non-opioid alternatives meet the criteria established at § 416.174. We welcome stakeholder comment on these evaluations.

a. Proposed Annual Eligibility Re-Evaluations of Non-Opioid Alternatives That Were Separately Paid in the ASC Setting During CY 2022

In the CY 2022 final rule with comment period, we finalized that four drugs would receive separate payment in the ASC setting for CY 2022 under

the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496). These drugs are described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), HCPCS code C9088 (*Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg),* and HCPCS code C9089 *(Bupivacaine, collagen-matrix implant, 1 mg*).

We re-evaluated these products outlined in the previous paragraph against the criteria specified in § 416.174, including the technical clarifications we propose to that section, to determine whether they continue to qualify for separate payment in CY 2023. Based on our evaluation, we propose that the drugs described by HCPCS codes C9290, J1097, and C9089 continue to meet the required criteria and should receive separate payment in the ASC setting. We propose that the drug described by HCPCS code C9088 would not receive separate payment in the ASC setting under this policy as this drug will be separately payable during CY 2023 under OPPS transitional pass-through status. Please see section V.A, ''OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals'' of this proposed rule for additional details on the pass-through status of HCPCS code C9088.

We welcome comment on our evaluations below.

(a) Proposed Eligibility Evaluation for the Separate Payment of Exparel

Based on our internal review, we believe that Exparel, described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), meets the criteria described at § 416.174, including the technical clarifications we propose to that section, and we propose to continue making separate payment for it under the ASC payment system for CY 2023. Exparel was approved by FDA with a New Drug Application (NDA #022496) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on October 28, 2011.[166] Exparel's FDA-approved indication is ''in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia'' and ''in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia''.[167] No component of Exparel is opioid-based. Accordingly, we propose that Exparel meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Exparel exceeds the proposed $135 per-day cost threshold. Therefore, we propose that Exparel meets the criterion described at § 416.174(a)(2). Additionally, Exparel will not have transitional pass-through payment status under § 419.64 in CY 2023, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2023 under a policy other than the one specified in § 416.174. Therefore, we propose that Exparel meets the criteria we propose to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we believe that Exparel meets the criteria described at § 416.174 and we propose to continue making separate payment for it as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(b) Proposed Eligibility Evaluation for the Separate Payment of Omidria

Based on our internal review, we believe that Omidria, described by HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), meets the criteria described at § 416.174(a), and we propose to continue making separate payment for it under the ASC payment system for CY 2023. Omidria was approved by FDA with a New Drug Application (NDA #205388) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on May 30, 2014.[168] Omidria's FDA-approved indication is as ''an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for: Maintaining pupil size by preventing intraoperative miosis; Reducing postoperative pain''.[169] No component of Omidria is opioid-based. Accordingly, we propose that Omidria meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a of this proposed rule, the per-day cost of Omidria exceeds the proposed $135 per-day cost threshold. Therefore, we propose that Omidria meets the criterion described at § 416.174(a)(2). Additionally, we believe that Omidria will not have transitional pass-through payment status under § 419.64 in CY 2023, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2023 under a policy other than the one specified in § 416.174. Therefore, we propose that if Omidria meets the criteria we propose to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we propose that Omidria meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(c) Proposed Eligibility Evaluation for the Separate Payment of Xaracoll

Based on our internal review, we believe Xaracoll, described by C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), meets the criteria described at § 416.174(a), and we propose to continue making separate payment for it under the ASC payment system for CY 2023. Xaracoll was approved by FDA with a New Drug Application (NDA # 209511) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on August 28, 2020.[170] Xaracoll is ''indicated in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair''.[171] No component of Xaracoll is opioid-based. Accordingly, we propose that Xaracoll meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Xaracoll exceeds the proposed $135 per-day cost threshold. Therefore, we propose that Xaracoll meets the criterion described at § 416.174(a)(2). Additionally, at this time we do not believe that Xaracoll will have transitional pass-through payment status under § 419.64 in CY 2023, nor do we believe it will otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we propose that if Xaracoll meets the criteria we propose to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we propose that Xaracoll meets the criteria

[166] Exparel. FDA Letter. 28 October 2011. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022496s000ltr.pdf.*

[167] Exparel. FDA Package Insert. 22 March 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s035lbl.pdf.*

[168] Omidria. FDA Letter. 30 May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205388Orig1s000ltr.pdf.*

[169] Omidria. FDA Package Insert. December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*

[170] Xaracoll. FDA Letter. August 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209511Orig1s000ltr.pdf.*

[171] Xaracoll. FDA Labeling. August 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf.*

described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(d) Proposed Eligibility Evaluation for the Separate Payment of Zynrelef

Zynrelef, the drug described by HCPCS code C9088 (*Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg*), received drug pass-through payment status as of April 1, 2022. As discussed above, our policy, as finalized in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), states that non-opioid pain management drugs and biologicals that function as supplies in surgical procedures that are already paid separately, or have transitional drug pass-through status under the OPPS, would not be candidates for this policy as they are already paid separately under the OPPS and ASC payment systems. Also discussed above, we propose to include this requirement as a technical change in new regulation text at § 416.174(a)(3). Zynrelef receives separate payment consistent with its drug pass-through approval and we have proposed in section V.A of this proposed rule that its pass-through status will not expire until after CY 2023. Accordingly, we propose that Zynrelef would not be eligible for separate payment under the ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies in CY 2023. Please see section V.A, ''OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals'' of this proposed rule for additional details on transitional drug pass-through payments.

b. Proposed Evaluations of Newly Eligible Non-Opioid Alternatives

In this section, we evaluate drugs or biologicals, of which we are aware, that we believe may be newly eligible for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply against the criteria described at § 416.174(a). We evaluated whether Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), a drug with pass-through status expiring December 31, 2022, meets the criteria specified in § 416.174, including the technical clarifications we propose to that section. We propose that Dextenza receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2023. We welcome stakeholder comment on this evaluation.

(a) Proposed Eligibility Evaluation for the Separate Payment of Dextenza

Based on our internal review, we believe Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), meets the criteria described at § 416.174 and we propose to provide separate payment for it under the ASC payment system for CY 2023. Dextenza was approved by FDA with a New Drug Application (NDA # 208742) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on November 30, 2018.[172] Dextenza's FDA-approved indication is as ''a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery'' and ''the treatment of ocular itching associated with allergic conjunctivitis''.[173] No component of Dextenza is opioid-based. Accordingly, we believe Dextenza meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Dextenza exceeds the proposed $135 per-day OPPS drug packaging cost threshold, so Dextenza also meets the criterion described at § 416.174(a)(2). Additionally, Dextenza's pass-through status expires on December 31, 2022, and we do not believe that it will otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we propose that if Dextenza meets the criteria we propose to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we propose that Dextenza meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

Table 60 below lists the four drugs that we propose to meet the criteria described at § 416.174 to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

[172] * Dextenza. FDA Letter. November 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000Approv.pdf.*

[173] Dextenza. FDA Labeling. October 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.*

TABLE60: SUMMARY OF PROPOSED PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2023

HCPCS Code	Long Descriptor	Proposed CY 2023 OPPS Status Indicator (SI)*	Proposed CY 2023 ASC Payment Indicator (PI)*
C9290	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	N	K2
C9089	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC Addenda BB for applicable proposed payment rates, OPPS Addenda D1 for proposed SI definitions, and ASC Addenda DD1 for proposed PI definitions. All are available via the internet on the CMS website.

4. Comment Solicitation Payment Policies for Separate Payment for Additional Drugs and Biologicals and Other Products That Function as Supplies in Surgical Procedures for CY 2023

We are soliciting comment on additional non-opioid pain management drugs and biologicals that function as surgical supplies that may meet the criteria specified in § 416.174 and therefore qualify for separate payment under the ASC payment system. We encourage commenters to include an explanation of how the drug or biological meets the eligibility criteria in § 416.174, including the technical clarifications we propose to that section. In the CY 2023 OPPS/ASC final rule with comment period, we will include a summary of comments we receive and our analysis of whether these products meet the eligibility criteria in § 416.174. If we find these additional drugs or biologicals do satisfy the criteria established at § 416.174, we will finalize their separate payment status for CY 2023 in the ASC setting in the CY 2023 OPPS/ASC final rule with comment period.

We are also seeking comment on potential policy modifications and additional criteria that may help further align the ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies with the intent of sections 1833(t)(22) and 1833(i)(8) of the Act. We also seek comment on non-drug or non-biological products that should qualify for separate, or modified, payment under this authority and any data regarding any such products. In addition, we solicit comments on barriers to access to non-opioid pain management products that may exist, and how our payment policies could be modified to address these barriers. We are also interested in comments and data regarding the need to expand the current ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies to the OPPS, which is discussed in section XIII.E.3 of this proposed rule.

We will take comments into consideration for potential future changes to this policy.

F. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

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 requested in the guidance document titled ''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 website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.*
- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant

characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2023

We did not receive any requests for review to establish a new NTIOL class for CY 2023 by March 1, 2022, the due date published in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63809).

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 do not propose to revise the payment adjustment amount for CY 2023.

G. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included 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 ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed 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, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if 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 this 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 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

2. Proposed ASC Payment and Comment Indicators for CY 2023

For CY 2023, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Proposed Category I and III CPT codes that are new and revised for CY 2023 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2023, compared to the CY 2022 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of the CY 2023 OPPS/ASC proposed rule.

We refer readers to Addenda DD1 and DD2 of this proposed rule (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2023 update.

H. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 ASC final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system

budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.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 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 ASC final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. 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.

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. 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. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*).

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–03 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf*. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf*.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*).

The proposed CY 2023 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 Nos. 13–01, 15–01, 17–01, 18–03, 18–04, and 20–01). 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 2023, we are applying

a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

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 apply 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. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2023 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS 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). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

As discussed in section II.A.1.a of this proposed rule, we are using the CY 2021 claims data to be consistent with the OPPS claims data for this proposed rule. Consistent with our established policy, we propose to scale the CY 2023 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 2021, we propose to compare the total payment using the CY 2022 ASC relative payment weights with the total payment using the CY 2023 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2022 and CY 2023. Additionally, in light of our proposal to provide a higher ASC payment rate through the use of new C codes for 52 primary procedures when performed with add-on packaged services, CY 2023 total payments will include spending and utilization related to these new C codes. For this proposed rule, we estimate the additional CY 2023 spending to be $5 million.

We propose to use the ratio of CY 2022 to CY 2023 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2023. The proposed CY 2023 ASC weight scalar is 0.8474. Consistent with historical practice, we would scale the ASC relative payment weights of 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. We propose to use the CY 2021 claims data to model our budget neutrality adjustment.

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 2023, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2021 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2023 ASC wage indexes. Specifically, holding CY 2021 ASC utilization, service-mix, and the proposed CY 2023 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2022 ASC wage indexes and the total adjusted payment using the proposed CY 2023 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 2022 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2023 ASC wage indexes and applied the resulting ratio of 1.0010 (the proposed CY 2023 ASC wage index budget neutrality adjustment) to the CY 2022 ASC conversion factor to calculate the proposed CY 2023 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. 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 § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we finalized our proposal to revise our regulations under § 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intended to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

The proposed hospital market basket update for CY 2023 is projected to be 2.7 percent, as published in the FY 2023 IPPS/LTCH PPS proposed rule (86 FR 25435), based on IHS Global Inc.'s (IGI's) 2021 fourth quarter forecast with historical data through the third quarter of 2021.

Section 1886(b)(3)(B)(xi)(II) of the 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). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2023 was projected to be 0.4 percentage point, as published in the FY 2023 IPPS/LTCH PPS proposed rule (86 FR 25435) based on IGI's 2021 fourth quarter forecast.

For CY 2023, we propose to utilize the hospital market basket update of 3.1 percent reduced by the productivity adjustment of 0.4 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 2.7 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.7 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2023 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E of this proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We propose to utilize the hospital market basket update of 3.1 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the 0.4 percentage point productivity adjustment. Therefore, we proposed to apply a 0.7 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also propose that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 ASC update for the final rule.

For CY 2023, we propose to adjust the CY 2022 ASC conversion factor ($49.916) by the proposed wage index budget neutrality factor of 1.0010 in addition to the productivity-adjusted hospital market basket update of 2.7 percent discussed above, which results in a proposed CY 2023 ASC conversion factor of $51.315 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2022 ASC conversion factor ($49.916) by the proposed wage index budget neutrality factor of 1.0010 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.7 percent discussed above, which results in a proposed CY 2023 ASC conversion factor of $50.315.

We request comments on our proposals for updating the CY 2023 ASC conversion factor.

3. Display of the Proposed CY 2023 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2023 for covered surgical procedures and covered ancillary services, respectively. The proposed payment rates included in Addenda AA and BB to this proposed rule reflect the full ASC proposed 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 2023 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 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

For CY 2021, we finalized adding a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled ''Proposed CY 2023 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2023. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures; services that are paid at the MPFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy

sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2023 payment rate displayed in the ''Proposed CY 2023 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2023 Payment Weight'' column was multiplied by the proposed CY 2023 conversion factor. The 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. The proposed CY 2023 ASC conversion factor uses the CY 2023 productivity-adjusted hospital market basket update factor of 2.7 percent (which is equal to the projected hospital market basket update of 3.1 percent reduced by a projected productivity adjustment of 0.4 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2023 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2023 Payment'' column displays the proposed CY 2023 national unadjusted ASC payment rates for all items and services. The proposed CY 2023 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 2021.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2023. Addendum FF displays the device offset percentages calculated under the standard ASC ratesetting methodology for covered surgical procedures in CY 2023.

Addendum FF to this proposed rule displays the OPPS payment rate (based on the standard ratesetting methodology), the device offset percentage, and the device portion of the ASC payment rate for CY 2023 for covered surgical procedures.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

We seek to promote higher quality, more efficient, and equitable healthcare for Medicare beneficiaries. Consistent with these goals, we have 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.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. In the CY 2021 OPPS/ASC final rule (85 FR 86179), we finalized updates to the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CYs 2008 through 2022 OPPS/ASC final rules for detailed discussions of the regulatory history of the Hospital OQR Program:

- The CY 2008 OPPS/ASC final rule (72 FR 66860 through 66875);
- The CY 2009 OPPS/ASC final rule (73 FR 68758 through 68779);
- The CY 2010 OPPS/ASC final rule (74 FR 60629 through 60656);
- The CY 2011 OPPS/ASC final rule (75 FR 72064 through 72110);
- The CY 2012 OPPS/ASC final rule (76 FR 74451 through 74492);
- The CY 2013 OPPS/ASC final rule (77 FR 68467 through 68492);
- The CY 2014 OPPS/ASC final rule (78 FR 75090 through 75120);
- The CY 2015 OPPS/ASC final rule (79 FR 66940 through 66966);
- The CY 2016 OPPS/ASC final rule (80 FR 70502 through 70526);
- The CY 2017 OPPS/ASC final rule (81 FR 79753 through 79797);
- The CY 2018 OPPS/ASC final rule (82 FR 59424 through 59445);
- The CY 2019 OPPS/ASC final rule (83 FR 59080 through 59110);
- The CY 2020 OPPS/ASC final rule (84 FR 61410 through 61420);
- The CY 2021 OPPS/ASC final rule (85 FR 86179 through 86187); and
- The CY 2022 OPPS/ASC final rule (86 FR 63822 through 63875).

We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. We refer readers to section XX.X of this proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2025 payment determination.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously finalized and codified at 42 CFR 419.46(h)(1) a policy to retain measures from the previous year's measure set for subsequent years, unless removed (77 FR 68471 and 83 FR 59082). We are not proposing any changes to these policies in this proposed rule.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Immediate Removal or Suspension

We previously finalized and codified at 42 CFR 419.46(i)(2) and (3) a process for removal or suspension of a Hospital OQR Program measure, based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 60634 through 60635, 77 FR 68472, and 83 FR 59082).[174] We are not proposing any changes to these policies in this proposed rule.

b. Consideration Factors for Removing Measures

We previously finalized and codified at 42 CFR 419.46(i)(3) policies to use the regular rulemaking process to remove a measure for circumstances other than when CMS believes that continued use of a measure raises specific patient safety concerns (74 FR 60635 and 83 FR 59082).[175] We are not proposing any changes to these policies in this proposed rule.

[174] We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68472 and 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program.

[175] We initially referred to this process as ''retirement'' of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to ''removal'' during final rulemaking.

4. Modifications to Previously Adopted Measures

a. Proposal To Change the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (OP–31) Measure From Mandatory to Voluntary Beginning With the CY 2027 Payment Determination

(1) Background

The OP–31 measure was adopted in the CY 2014 OPPS/ASC final rule (78 FR 75102 and 75103). During CY 2014 OPPS/ASC rulemaking, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75103). In response to those comments, we modified our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden by applying a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75113 through 75115). Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey, and we were unclear about the impact the use of varying surveys might have on accuracy, feasibility, or reporting burden. Therefore, we issued guidance[176] stating that we would delay the implementation of OP–31, and we subsequently finalized in the CY 2015 OPPS/ASC final rule (79 FR 66947) the exclusion of OP–31 from the measure set while allowing hospitals to voluntarily report measure data beginning with the CY 2015 reporting period.

(2) Considerations Concerning Previously Finalized OP–31 Measure Requirements Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2022 OPPS/ASC proposed rule (86 FR 42247), we stated that it would be appropriate to require that hospitals report on OP–31 for the CY 2023 reporting period/CY 2025 payment determination as hospitals have had the opportunity for several years to familiarize themselves with OP–31, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period. Many commenters expressed concern about making this measure mandatory due to the burden of reporting the measure and the impact this additional burden would have during the COVID–19 pandemic, stating that OP–31 has not been mandatory and many facilities have not been practicing reporting it (86 FR 63845). In response to these comments, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a delay in the implementation of this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination (86 FR 63845 through 63846).

Since the publication of the CY 2022 OPPS/ASC final rule with comment period, interested parties have expressed concern about the reporting burden of this measure given the ongoing COVID–19 public health emergency (PHE). Interested parties have indicated that they are still recovering from the COVID–19 PHE and that the requirement to report OP–31 would be burdensome due to national staffing and medical supply shortages coupled with unprecedented changes in patient case volumes. Due to the continued impact of the COVID–19 PHE, such as national staffing and medical supply shortages, the 2-year delay of mandatory reporting for this measure is no longer sufficient. Based on these factors and the feedback we received from interested parties, we believe it is appropriate to change OP–31 from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. A hospital would not be subject to a payment reduction for failing to report this measure during the voluntary reporting period; however, we strongly encourage hospitals to gain experience with the measure. We plan to continue to evaluate this policy moving forward. To be clear, there are no changes to reporting for the CY 2023 and CY 2024, during which the measure would remain voluntary.

As the OP–31 measure uniquely requires cross-setting coordination among clinicians of different specialties (that is, surgeons and opthalmologists), we believe it appropriate to defer mandatory reporting at this time. We will consider mandatory reporting of OP–31 after the national PHE declaration officially ends and we find it appropriate to do so given COVID–19 PHE impacts on national staffing and supply shortages. We intend to consider implementation of mandatory reporting of the OP–31 measure through future rulemaking because as we noted in the CY 2015 OPPS/ASC final rule, this measure addresses an area of care that is not adequately addressed in our current measure set and the measure serves to drive the coordination of care (79 FR 66947). We subsequently stated in the CY 2022 OPPS/ASC final rule with comment period that while the measure has been voluntary and available for reporting since the CY 2015 reporting period, a number of facilities have reported data for this measure and those that have reported these data have done so consistently (86 FR 63845).

We invite public comment on this proposal.

5. Previously Finalized and Proposed Hospital OQR Program Measure Sets

a. Previously Finalized Hospital OQR Program Measure Set for the CY 2024 Payment Determination

We refer readers to the CY 2022 OPPS/ASC final rule (85 FR 63846 through 63850) for a summary of the previously adopted Hospital OQR Program measure set for the CY 2024 payment determination and subsequent years. Table 61 summarizes the previously finalized Hospital OQR Program measure set for the CY 2024 payment determination:

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[176] *See* Letter from Craig Bryant to Hospital OQR initiative discussions re: Outpatient Quality Reporting (OQR) Program—Delay of New Measures (Dec. 31, 2013), available at *https://qualitynet.cms.gov/files/5d3792e74b6d1a256059d87d?filename=2013-40-OP.pdf*; *see also* Letter from Craig Bryant to Hospital OQR initiative discussions re: Delayed Implementation of OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery Measure (NQF #1536) to January 1, 2015; Data Collection Period for Two Endoscopy Measures OP–29 and OP–30 Begins (April 2, 2014), available at *https://qualitynet.cms.gov/files/5d3793174b6d1a256059d8e3?filename=2014-14-OP,0.pdf.*

TABLE 61: Hospital OQR Program Measure Set for the CY 2024 Payment Determination

NQF #	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*
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
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
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
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
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-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates

† We note that NQF endorsement for this measure was removed.

* In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63824), we finalized removal of the (Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3) measures beginning with the CY 2023 reporting period/CY 2025 payment determination. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63824) for more detail on how the OP-2 and OP-3 measures will be replaced by the STEMI-eCQM (OP-40).

**OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule (79 FR 66946 and 66947). In the CY 2022 OPPS/ASC final rule comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination.

b. Summary of Proposed Hospital OQR Program Measure Set for the CY 2025 Payment Determination

Table 62 summarizes the Hospital OQR Program measure set including our proposal in this proposed rule for the CY 2025 payment determination:

TABLE 62: Hospital OQR Program Measure Set for the CY 2025 Payment Determination

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
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
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
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
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: Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (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**
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-40: ST-Segment Elevation Myocardial Infraction (STEMI) electronic clinical quality measure (eCQM)***

† We note that NQF endorsement for this measure was removed.

* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule (79 FR 66946 and 66947). In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination. In this proposed rule, we propose that data collection and submission remain voluntary for this measure for the CY 2025 reporting period and subsequent years.

** In the CY 2022 OPPS/ASC final rule with comment period(86 FR 63840) we finalized voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

*** The STEMI eCQM (OP-40) was adopted in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and for mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

c. Summary of Proposed Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

Table 63 summarizes the proposed Hospital OQR Program measure set for the CY 2026 payment determination and subsequent years:

TABLE 63: Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
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
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
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
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**
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM***

† We note that NQF endorsement for this measure was removed.
* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 and 66947). In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination. In this proposed rule, we propose that data collection and submission remain voluntary for this measure for the CY 2025 reporting period and subsequent years.
** In the CY 2022 OPPS/ASC final rule with comment period(86 FR 63840), we finalized voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.
*** The STEMI eCQM (OP-40) was adopted in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

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6. Hospital OQR Program Measures and Topics for Future Considerations

a. Request for Comment on Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) Measure or Adoption of Another Volume Indicator

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings, and since 1983, inpatient stays per capita have fallen by 31 percent.[177] In line with this trend, outpatient services increased by 0.7 percent in 2019 while inpatient services decreased by 0.9 percent. [178] Research indicates that volume in hospital outpatient departments will continue to grow, with some estimates projecting a 19 percent increase in patients between 2019 and 2029.[179]

Volume has a long history as a quality metric, however, quality measurement efforts moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes.[180] While studies suggest that larger facility surgical procedure volume does not alone lead to better outcomes, it may be associated with better outcomes due to having characteristics that improve care (for example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications), making volume an important component of quality.[181] The

[177] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.*

[178] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.*

[179] Sg2. Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. June 4, 2021. Available at: *https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/.*

[180] Jha AK. Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015.

[181] Auerbach AD et al. The Relationship between Case-Volume, Care Quality, and Outcomes of Complex Cancer Surgery. Journal of the American

Hospital OQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but did so previously. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74466 through 74468) where we adopted the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure (OP–26) beginning with the CY 2012 reporting period/CY 2014 payment determination. This structural measure of facility capacity collected surgical procedure volume data on eight categories of procedures frequently performed in the hospital outpatient setting: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin (76 FR 74466). We adopted OP–26 based on evidence that the volume of surgical procedures, and particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality (76 FR 74466).[182] [183] [184] This may be attributable to greater experience or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74467).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59429), we removed OP–26, stating that there is a lack of evidence to support this specific measure's link to improved clinical quality. Although there is evidence of a link between patient volume and better patient outcomes, we stated that we believed that there was a lack of evidence that this link was reflected in the OP–26 measure specifically. Based on this belief, we removed the OP–26 measure under the following measure removal criterion: performance or improvement on a measure does not result in better patient outcomes. At the time, many commenters supported the proposal to remove the OP–26 measure (82 FR 59429).

We are considering reimplementing the OP–26 measure or another volume measure because the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures.

Over the past few decades, innovations in the health care system have driven the migration of procedures from the inpatient setting to the outpatient setting. Forty-five percent of percutaneous coronary intervention (PCI) procedures shifted from the inpatient to outpatient setting from 2004 to 2014, and more than 70 percent of patients who undergo thoracoscopic surgery can be discharged on the day of the surgery itself due to the use of innovative techniques and technologies available in the outpatient setting. [185] [186] Given these developments, we believe that patients may benefit from the public reporting of facility-level volume measure data that reflect the procedures performed across hospitals and provide the ability to track volume changes by facility and procedure category. Volume is an indicator for patients of which facilities are experienced with certain outpatient procedures.

OP–26 was the only measure in the Hospital OQR Program measure set that captured facility-level volume within hospitals and volume for Medicare and non-Medicare patients. As a result of its removal, the Hospital OQR Program currently does not capture outpatient surgical procedure volume in hospitals.

Furthermore, we are considering the reintroduction of a facility-level volume measure to support potential future development of a pain management measure, as described in a request for comment in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63902 through 63904). When considering the need for a pain management measure, we analyzed volume data to determine the proportion of ASC procedures performed for pain management using the methodology established by ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures, the volume measure that was included in the ASCQR Program measure set (76 FR 74507 through 74509). We found that pain management procedures were the third most common procedure in CY 2019 and 2020 and concluded that a pain management measure would provide consumers with important quality of care information. Thus, a volume measure in the Hospital OQR Program's measure set would provide information to Medicare beneficiaries and other interested parties on numbers and proportions of procedures by category performed by individual facilities, including for hospital outpatient procedures related to pain management.

We note that the OP–26 measure was adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 4466 through 74468) and was not reviewed or endorsed by the Measure Applications Partnership (MAP), which first began its pre-rulemaking review of quality measures across Federal programs in February 2012, after the publication of the CY 2012 OPPS/ASC final rule with comment period in November 2011.[187] Therefore, for OP–26 to be adopted in the Hospital OQR Program measure set, the measure would need to first undergo the pre-rulemaking process specified in section 1890A(a) of the Act.

Solicitation of Comments on the Readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) Measure or Other Volume Indicator in the Hospital OQR Program

We seek comment on the potential inclusion of a volume measure in the Hospital OQR Program, either by re-adopting the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) measure or adopting another volume indicator. We also seek comment on what volume data hospitals currently collect and if it is feasible to submit this data to the Hospital OQR Program, to minimize the collection and reporting burden of an alternative, new volume measure. Additionally, we seek comment on an appropriate timeline for implementing and publicly reporting the measure data.

Specifically, we invite comment on the following:

- The usefulness of including a volume indicator in the Hospital OQR Program measure set and publicly reporting volume data.

College of Surgery. 2010;211(5):601–608. doi:10.1016/j.jamcollsurg.2010.07.006.

[182] Livingston, E.H.; Cao, J ''Procedure Volume as a Predictor of Surgical Outcomes''. Edward H. Livingston, Jing Cao JAMA. 2010;304(1):95–97.

[183] David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. ''Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures''. *JAMA. 2005;294(15):1903–1908.*

[184] Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B '' Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer'' *JAMA. 2000; 284 (23): 3028–3035.*

[185] Abrams KD, Balan-Cohen A, Durbha P. Growth in Outpatient Care: The role of quality and value incentives. Deloitte Insights. 2018. Available at: *https://www2.deloitte.com/us/en/insights/industry/health-care/outpatient-hospital-services-medicare-incentives-value-quality.html.*

[186] Chang AC, Yee J, Orringer MB, Iannettoni MD. Diagnostic thoracoscopic lung biopsy: an outpatient experience. The Annals of Thoracic Surgery. 2002;74:1942–7.

[187] Measures Application Partnership. Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking Final Report. February 2012. Available at: *https://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx.*

• Input on the mechanism of volume data collection and submission, including anticipated barriers and solutions to data collection and submission.

• Considerations for designing a volume indicator to reduce collection burden and improve data accuracy.

• Potential reporting of volume by procedure type, instead of total surgical procedure volume data for select categories, and which procedures would benefit from volume reporting.

• The usefulness of Medicare versus non-Medicare reporting versus other or additional categories for reporting.

b. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

Significant and persistent inequities in healthcare outcomes exist in the United States. Belonging to a racial or ethnic minoritized group; being a member of a religious minority; living with a disability; being a member of lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level is often associated with worse health outcomes. [188] [189] [190] [191] [192] [193] [194] [195] [196]

One approach being employed to reduce inequity across our programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables. The Request for Information (RFI) included in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28479), titled ''Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs'' describes key considerations that we might take into account across all CMS quality programs, including the Hospital OQR Program, when advancing the use of measure stratification to address healthcare disparities and advance health equity across our programs.

We ask that readers review the full RFI in the FY 2023 IPPS/LTCH PPS proposed rule for full details on these considerations. For comments and feedback on the application of these principles to the Hospital OQR Program, please respond to this proposed rule.

7. 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 website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 and 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019, such that we will release a manual once every 12 months and release addenda as necessary.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63861), we finalized the adoption of eCQMs into the Hospital OQR Program measure set beginning with the CY 2023 reporting period and finalized the manner to update the technical specifications for eCQMs. Technical specifications for eCQMs used in the Hospital OQR Program will be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/*. For eCQMs, we will update the measure specifications on an annual basis through the Annual Update which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and electronic health record (EHR) vendors to use in order to collect and submit data on eCQMs from hospital EHRs. We are not proposing any changes to these policies in this proposed rule.

8. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures. We are not proposing any changes to these policies in this proposed rule.

C. Administrative Requirements

1. QualityNet Account and Security Official

We refer readers to the CYs 2011, 2012, 2014 and 2022 OPPS/ASC final rules (75 FR 72099; 76 FR 74479; 78 FR 75108 through 75109; and 86 FR 639040, respectively) for the previously finalized QualityNet security official requirements, including those for setting up a QualityNet account and the associated timelines. These procedural requirements are codified at 42 CFR 419.46(b). Hospitals will be required to register and submit quality data through the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal). The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information. We are not proposing any changes to these policies in this proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CYs 2014, 2016, and 2019 OPPS/ASC final rules (78 FR 75108 through 75109; 80 FR 70519; and 83 FR 59103 through 59104, respectively) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these requirements at 42 CFR 419.46(b) and (c). We are not proposing any changes to these policies in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission deadlines. We codified these

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[189] Milkie Vu et al. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. J Womens Health (Larchmt). 2016 Jun;25(6):586–93. doi: 10.1089/jwh.2015.5517. Epub 2016 Feb 18. PMID: 26890129; PMCID: PMC5912720.

[190] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and 30-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. *British Medical Journal,* 346.

[191] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. *New England Journal of Medicine,* 371(24):2298–2308.

[192] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. *Health Affairs,* 40(2): 307–316.

[193] Rural Health Research Gateway. (2018). Rural communities: age, income, and health status. *Rural Health Research Recap. https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[194] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[195] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[196] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. *medRxiv.* 2020;2020.07.21. 20159327. doi:10.1101/2020.07.21.20159327.

submission requirements at 42 CFR 419.46(d).

a. Proposal To Align Hospital OQR Program Patient Encounter Quarters for Chart-Abstracted Measures to the Calendar Year for Annual Payment Update (APU) Determinations

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 and 75111), we specified our data submission deadlines and codified our submission requirements at 42 CFR 419.46(d)(2).[197] We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 and 70520), where we shifted the quarters on which the Hospital OQR Program payment determinations are based, beginning with the CY 2018 payment determination. Prior to the adoption of this policy, the previous timeframe had extended from patient encounter quarter three of 2 years prior to the payment determination to patient encounter quarter two of the year prior to the payment determination. This timeframe provided less than two months between the time that the data was submitted for validation and the beginning of the payments that are affected by these data, creating compressed processing times for CMS and compressed timelines for hospitals to review their APU determination decisions. To address this issue, we changed the timeframe to begin with patient encounter quarter two of 2 years prior to the payment determination and end with patient encounter quarter one of the year prior to the payment determination.

As finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 and 70520), the patient encounter quarters for chart-abstracted measures data submitted to the Hospital OQR Program are not aligned with the January through December calendar year. Because these quarters are not aligned with the calendar year, as other CMS quality programs' quarters are such as the Hospital Inpatient Quality Reporting (IQR) Program,[198] this misalignment has resulted in confusion among some hospitals regarding submission deadlines and data reporting quarters.

(2) Proposal To Align Hospital OQR Program Patient Encounter Quarters for Chart-Abstracted Measures to the Calendar Year Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

Beginning with the CY 2024 reporting period/CY 2026 payment determination, we propose to align the patient encounter quarters for chart-abstracted measures with the calendar year. If this proposal is finalized as proposed, all four quarters of patient encounter data for chart-abstracted measures would be based on the calendar year two years prior to the payment determination year. We propose this change to align the patient encounter quarters for chart-abstracted measures with the calendar year schedule of the Hospital OQR Program and to further align these quarters with those of the Hospital IQR Program since some hospitals may be submitting data for both programs. The Hospital IQR Program's patient encounter quarters all occur on the calendar year 2 years prior to the payment determination year as finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 through 50221). We believe that the proposed alignment would also provide more time for APU determinations by increasing the length of time between the last clinical data submission deadline and APU determinations.

As an example, the current and proposed patient encounter quarters and clinical data submission deadlines for the CY 2028 payment determination are illustrated in Tables 64 and 65, respectively.

[197] The CY 2014 OPPS/ASC final rule codified this standard in § 419.46(c)(2). This provision was moved to its current location in the CY 2021 OPPS/ASC final rule with comment period.

[198] FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 and 50221).

TABLE 64: Current CY 2028 Payment Determination*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2026 (April 1 - June 30)	11/1/2025**
Q3 2026 (July 1 – September 30)	2/1/2026**
Q4 2026 (October 1 - December 31)	5/1/2026**
Q1 2027 (January 1 - March 31)	8/1/2026**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 65: Proposed CY 2028 Payment Determination*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2026 (January 1 - March 31)	8/1/2026**
Q2 2026 (April 1 - June 30)	11/1/2026**
Q3 2026 (July 1 – September 30)	2/1/2027**
Q4 2026 (October 1 - December 31)	5/1/2027**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.
**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

To facilitate this process, we propose to transition to the newly proposed timeframe for the CY 2026 payment determination and subsequent years and use only three quarters of data for chart-abstracted measures in determining the CY 2025 payment determination as illustrated in the tables 66, 67, and 68 below. However, we note that data submission deadlines would not change.

TABLE 66: CY 2024 Payment Determination* (Current state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2022 (April 1 - June 30)	11/1/2023**
Q3 2022 (July 1 – September 30)	2/1/2024**
Q4 2022 (October 1 - December 31)	5/1/2024**
Q1 2023 (January 1 - March 31)	8/1/2024**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 67: Proposed CY 2025 Payment Determination*(Future state—transition period)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2023 (April 1 - June 30)	11/1/2023**
Q3 2023 (July 1 – September 30)	2/1/2024**
Q4 2023 (October 1 - December 31)	5/1/2024**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 68: Proposed CY 2026 Payment Determination* (Future state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 - March 31)	8/1/2024**
Q2 2024 (April 1 - June 30)	11/1/2024**
Q3 2024 (July 1 – September 30)	2/1/2025**
Q4 2024 (October 1 - December 31)	5/1/2025**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.
**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

We seek public comment on our proposal.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) and the QualityNet website available at: *https://qualitynet.cms.gov* for a discussion of the requirements for chart-abstracted measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

3. Claims-Based Measure Data Requirements

We refer readers to the CY 2019 OPPS/ASC final rule (83 FR 59106 through 59107), where we established a three-year reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63863) where we finalized a three-year reporting period for the Breast Cancer Screening Recall Rates measure (OP–39). We are not proposing any changes to these policies in this proposed rule.

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

We refer readers to the CYs 2017, 2018, and 2022 OPPS/ASC final rules (81 FR 79792 through 79794; 82 FR 59432 and 59433; and 86 FR 63863 through 63866, respectively) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures.

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63863 through 63866), where we reaffirmed our approach to the form, manner, and timing which OAS CAHPS information will be submitted with two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents), beginning with voluntary data collection for the CY 2023 reporting period/CY 2025 payment determination and continuing for mandatory reporting for subsequent years. For more information about the modes of administration, we refer readers to the OAS CAHPS Survey website: *https://oascahps.org/*. We are not proposing any changes to these policies in this proposed rule.

5. Data Submission Requirements for Measures Submitted via a Web Based Tool

a. Data Submission Requirements for Measures Submitted via a CMS Web-Based Tool

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule (80 FR 70521), and the QualityNet website available at: *https://qualitynet.cms.gov* for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

b. Data Submission Requirements for Measures Submitted via the CDC NHSN Website

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. In addition, we refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63866), where we finalized the adoption of the COVID–19

Vaccination Coverage Among Health Care Personnel measure (OP–38) beginning with the CY 2022 reporting period/CY 2024 payment determination. We are not proposing any changes to these policies in this proposed rule.

6. eCQM Reporting and Submission Requirements

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75106 and 75107), the CY 2015 OPPS/ASC final rule (79 FR 66956 through 66961), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70516 through 70518), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79785 through 79790), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59435 through 59438), and the CY 2022 OPPS/ASC final rule with comment period (82 FR 63867 through 63870) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including support for the introduction of eCQMs into the Program. Measure stewards and developers have worked to advance eCQMs that would be reported in the outpatient setting.

b. eCQM Reporting and Data Submission Requirements

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63867), we finalized the adoption of the STEMI eCQM (OP–40). In the CY 2022 OPPS/ASC final rule with comment period and a progressive increase in the number of quarters for which hospitals must report eCQM data (86 FR 63867 and 63868). For the CY 2023 reporting period, we finalized that hospitals submit STEMI eCQM (OP–40) data during this reporting period voluntarily for any quarter (86 FR 63868). Hospitals that choose to submit data voluntarily must submit in compliance with the eCQM certification requirements in sections XV.D.6.c, XV.D.6.d, and XV.D.6.e of the CY 2022 OPPS/ASC final rule with comment period. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63867 and 63868) for additional detail on the eCQM reporting and data submission requirements.

We also refer readers to Table 69 for a summary of the previously finalized quarterly data increase in eCQM reporting beginning with the CY 2023 reporting period.

TABLE 69: Progressive Increase in eCQM Reporting Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting
CY 2023 Reporting Period/CY 2025 Payment Determination	Any quarter(s)	Voluntary
CY 2024 Reporting Period/CY 2026 Payment Determination	One self-selected quarter	Mandatory
CY 2025 Reporting Period/CY 2027 Payment Determination	Two self-selected quarters	Mandatory
CY 2026 Reporting Period/CY 2028 Payment Determination	Three self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination and Subsequent Years	Four quarters (one calendar year)	Mandatory

c. Electronic Quality Measure Certification Requirements for eCQM Reporting

(1) Use of Cures Update

In May 2020, the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (ONC 21st Century Cures) Act final rule (85 FR 25642 through 25961) finalized updates to the health IT certification criteria (herein after referred to as the ''Cures Update''). These updates included revisions to the clinical quality measurement certification criterion at 45 CFR 170.315(c)(3) to refer to CMS Quality Reporting Data Architecture (QRDA) Implementation Guides and removal of the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25645). The ONC 21st Century Cures Act final rule provided health IT developers with up to 24 months from May 1, 2020 to make available to their customers technology certified to the updated and/or new criteria (85 FR 25670). In November 2020, ONC issued an interim final rule (85 FR 70064) which extended the compliance deadline for the clinical quality measures-report criterion at 45 CFR 170.315(c)(3) until December 31, 2022 (85 FR 70075). These updates were finalized to reduce burden on health IT developers (85 FR 70075) and have no impact on providers' existing reporting practices for the Hospital OQR Program.

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63868 and 63869), where we finalized the requirement for hospitals participating in the Hospital OQR Program to utilize certified technology updated consistent with the Cures Update for the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. This period includes both the voluntary reporting period and mandatory reporting periods. We noted that this requirement is in alignment with the Hospital IQR Program, which requires use of technology updated consistent with the Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination (See 86 FR 45418). We are not proposing any changes to these policies in this proposed rule.

d. File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for EHR Data

Data can be collected in EHRs and health information technology systems using standardized formats to promote consistent representation and interpretation, as well as to allow for systems to compute data without needing human interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standard details how data should be represented and the relationships between data elements.

We refer reader to the CY 2022 OPPS/ASC final rule with comment period (86 FR 42262), where we finalized, beginning with the CY 2023 reporting period/CY 2025 payment determination, that hospitals: (1) Must submit eCQM data via the QRDA Category I (QRDA I) file format; [199] (2) may use third parties

[199] QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to

to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I files. We also refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for discussion on the maintenance of technical specifications including those for eCQMs. We are not proposing any changes to these policies in this proposed rule.

(2) Zero Denominator Declarations

We understand there may be situations in which a hospital does not have data to report on a particular eCQM. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869), where we finalized that if the hospital's EHR is certified to an eCQM, but the hospital does not have patients that meet the denominator criteria of that eCQM, the hospital can submit a zero in the denominator for that eCQM. Submission of a zero in the denominator for an eCQM counts as a successful submission for that eCQM for the Hospital OQR Program (86 FR 63869). We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for additional detail on the zero denominator declarations policy. We are not proposing any changes to these policies in this proposed rule.

(3) Case Threshold Exemptions

We understand that in some cases, a hospital may not meet the case threshold of discharges for a particular eCQM. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869), we finalized a policy aligning the Hospital OQR Program case threshold exemption with the case threshold exemption from the Medicare Promoting Interoperability Program (77 FR 54080) and the Hospital IQR Program (79 FR 50324). Specifically, for the Hospital OQR Program we finalized that beginning with the CY 2023 reporting period/CY 2025 payment determination, if a hospital's EHR system is certified to report an eCQM and the hospital experiences five or fewer outpatient discharges per quarter or 20 or fewer outpatient discharges per year (Medicare and non-Medicare combined), as defined by an eCQM's denominator population, that hospital could be exempt from reporting on that eCQM (86 FR 63869). We also stated that the exemption would not have to be used; a hospital could report those individual cases if it would like to. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for additional detail on the case threshold exemption policy. We are not proposing any changes to these policies in this proposed rule.

e. Submission Deadlines for eCQM Data

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870), we finalized the policy to require eCQM data submission by May 15 of the following year for the applicable CY reporting period, beginning with the CY 2023 reporting period/CY 2025 payment determination. For example, CY 2023 eCQM data would need to be reported to us by May 15, 2024. We note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday. We refer reads to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) for additional detail on submission deadlines for eCQM data. We are not proposing any changes to these policies in this proposed rule.

7. Population and Sampling Data Requirements for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule (76 FR 74482 through 74483) for discussions of our population and sampling requirements. We are not proposing any changes to these policies in this proposed rule.

8. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule (79 FR 66964 and 67014) where we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. We are not proposing any changes to these policies in this proposed rule.

b. Web-Based Measures

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86184), we finalized an expansion of our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2021 reporting period/CY 2023 payment determination. We are not proposing any changes to these policies in this proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) where we finalized that hospitals have a review and corrections period for eCQM data submitted to the Hospital OQR Program. We finalized a review and corrections period for eCQM data which would run concurrently with the data submission period. We refer readers to the QualityNet website (available at: *https://qualitynet.cms.gov/outpatient/measures/eCQM*) and the eCQI Resource Center (available at: *https://ecqi.healthit.gov/*) for more resources on eCQM reporting. We are not proposing any changes to these policies in this proposed rule.

d. OAS CAHPS Measures

Each hospital administers (via its vendor) the survey for all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870). As finalized in the CY 2017 OPPS/ASC final rule with comment period, data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79793). We are not proposing any changes to these policies in this proposed rule.

9. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72105 through 72106), the CY 2013 OPPS/ASC final rule (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule (80 FR 70524), the CY 2018 OPPS/ASC final rule (82 FR 59441 through 59443), the CY 2022 OPPS/ASC final rule (86 FR 63870 through 63873), and 42 CFR 419.46(f) for our policies regarding validation.

b. Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests

In the CY 2022 OPPS/ASC final rule (86 FR 63870), we finalized discontinuing the option for hospitals to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation affecting the CY 2022

exchange eCQM data between systems. For further detail on QRDA I, the most recently available QRDA I specifications and Implementation Guides (IGs) can be found at: *https://ecqi.healthit.gov/qrda*.

reporting period/CY 2024 payment determination. Hospitals must instead submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures. Under this policy, hospitals are required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process as directed by the CMS Data Abstraction Center (CDAC). We would continue to reimburse hospitals at $3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts. We note that this process aligns with that for the Hospital IQR Program (See FY 2021 IPPS/LTCH PPS final rule, 85 FR 58949). We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63870) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests. We are not proposing any changes to these policies in this proposed rule.

c. Time Period for Chart-Abstracted Measure Data Validation

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPPS/ASC final rule (78 FR 75117 through 75118) and codified at 42 CFR 419.46(f)(1) for the CY 2025 payment determination and subsequent years.

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63871) where we finalized the revision of 42 CFR 419.46(f)(1) to change the time period given to hospitals to submit medical records to the CDAC contractor from 45 calendar days to 30 calendar days, beginning with medical record submissions for encounters in Q1 of CY 2022 affecting the CY 2024 payment determination and for subsequent years. We are not proposing any changes to these policies in this proposed rule.

d. Targeting Criteria

(1) Background

In the CY 2012 OPPS/ASC final rule (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 specific criteria. We finalized a policy in the CY 2013 OPPS/ASC final rule (77 FR 68485 and 68486), that for the CY 2014 payment determination and subsequent years, a hospital will be preliminarily selected for validation based on targeting criteria if it fails the validation requirement that applies to the previous year's payment determination. We also refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68486 and 68487) for a discussion of finalized policies regarding our medical record validation procedure requirements. In the CY 2018 OPPS/ASC final rule (82 FR 59441), for the targeting criterion ''the hospital has an outlier value for a measure based on the data it submits,'' we clarified that an ''outlier value'' for purposes of this criterion is defined as a measure value that appears to deviate markedly from the measure values for other hospitals. In the CY 2022 OPPS/ASC final rule (86 FR 63872), we finalized the addition of two targeting criteria: any hospital that has not been randomly selected for validation in any of the previous three years or any hospital that passed validation in the previous year and had a two-tailed confidence interval that included 75 percent. We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63872) for additional information on the Hospital OQR Program's previously finalized targeting criteria.

We have codified at 42 CFR 419.46(f)(3) that we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals for validation purposes based on the following targeting criteria:

- The hospital fails the validation requirement that applies to the previous year's payment determination; or
- 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 five standard deviations from the mean of the measure values for other hospitals and indicates a poor score; or
- The hospital has not been randomly selected for validation in any of the previous three years; or
- The hospital passed validation in the previous year but had a two-tailed confidence interval that included 75 percent.

(2) Proposed Addition of Targeting Criterion

Beginning with validations affecting the CY 2023 reporting period/CY 2025 payment determination, we propose to add a new criterion to the four established targeting criteria at § 419.46(f)(3) used to select the 50 additional hospitals. We propose that a hospital with less than four quarters of data subject to validation due to receiving an ECE for one or more quarters and with a two-tailed confidence interval that is less than 75 percent would be targeted for validation in the subsequent validation year. We propose this additional criterion because such a hospital would have less than four quarters of data available for validation and its validation results could be considered inconclusive for a payment determination. Hospitals that meet this criterion would be required to submit medical records to the CDAC contractor within 30 days of the date identified on the written request as finalized in the CY 2022 OPPS/ASC final rule (86 FR 63871) and codified at § 419.46(f)(1).

It is important to clarify that, consistent with our previously finalized policy, a hospital is subject to both payment reduction and targeting for validation in the subsequent year if it either: (a) has less than four quarters of data, but does *not* have an ECE for one more or more quarters and does not meet the 75 percent threshold; or (b) has four quarters of data subject to validation and does not meet the 75 percent threshold.

Specifically, we propose to revise 42 CFR 419.46(f)(3) to add the following criterion for targeting the additional 50 hospitals for validation:

- Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters.

Our proposal would allow us to appropriately address instances in which hospitals that submit fewer than four quarters of data due to receiving an ECE for one or more quarters might face payment reduction under the current validation policies. We invite public comment on our proposal.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59441 through 59443) and the CY 2021 OPPS/ASC final rule (85 FR 86185) where we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. We are not proposing any changes to these policies in this proposed rule.

9. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68489), the CY 2014 OPPS/ASC final rule (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule (79 FR 66966), the CY 2016 OPPS/ASC final rule (80 FR 70524), the CY 2017 OPPS/ASC final rule (81 FR 79795), the CY 2018 OPPS/ASC final rule (82 FR 59444), the CY 2022 OPPS/ASC final rule (86 FR 63873), and 42 CFR 419.46(e) for a complete discussion of our

extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We are not proposing any changes to these policies in this proposed rule.

10. Hospital OQR Program Reconsideration and Appeals Procedures

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule (80 FR 70524), the CY 2017 OPPS/ASC final rule (81 FR 79795), the CY 2021 OPPS/ASC final rule (85 FR 68185), and 42 CFR 419.46(g) for our reconsideration and appeals procedures. We are not proposing any changes to these policies in this proposed rule.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2023 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the internet on the CMS website): ''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 rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor − 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor − 0.02)/(1 + OPD update factor)

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. Reporting Ratio Application and Associated Adjustment Policy for CY 2023

We propose 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 2023 annual payment update factor. For this CY 2023 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of $86.785, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $85.093. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We propose to continue 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 assignments of ''S'' and ''T''). We propose to continue to exclude services paid under New Technology APCs. We propose 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 propose 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 propose 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. In addition to our proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2023, the proposed reporting ratio is 0.9805, which, when multiplied by the final full conversion factor of $86.785, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $85.093.

XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1 of the CY 2020 OPPS/ASC final rule (84 FR 61410) for a general overview of our outpatient quality reporting programs.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule (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 refer readers to the CYs 2014 through 2022 OPPS/ASC final rules for an overview of the regulatory history of the ASCQR Program:

- CY 2014 OPPS/ASC final rule (78 FR 75122);
- CY 2015 OPPS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPPS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPPS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPPS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPPS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPPS/ASC final rule (84 FR 61420 through 61434);
- CY 2021 OPPS/ASC final rule (85 FR 86187 through 86193); and
- CY 2022 OPPS/ASC final rule (86 FR 63875 through 63911).

We have codified requirements under the ASCQR Program in 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330).

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68493 and 68494) for a detailed discussion of the priorities we consider for the ASCQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy to retain measures from the previous year measure set for subsequent years, except when such measures are removed (76 FR 74494 and 74504; 77 FR 68494 and 68495; 78 FR 75122; and 79 FR 66967 through 66969). We are not proposing any changes to this policy in this proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule (83 FR 59111 through 59115), we finalized and codified at 42 CFR 416.320 an updated set of factors and the process for removing measures from the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

3. Proposal To Change the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (ASC–11) Measure From Mandatory to Voluntary Beginning With the CY 2027 Payment Determination

a. Background

The ASC–11 measure was adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129). During CY 2014 OPPS/ASC rulemaking, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75129). In response to those comments, we modified our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden by applying a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75129). Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess

visual function. The measure specifications allowed for the use of any validated survey, and we were unclear about the impact the use of varying surveys might have on accuracy, feasibility, or reporting burden. Therefore, we issued guidance stating that we would delay the implementation of ASC–11, and we subsequently finalized in the CY 2015 OPPS/ASC final rule (79 FR 66983 through 66985) the exclusion of ASC–11 from the required measure set while allowing ASCs to voluntarily report measure data beginning with the CY 2015 reporting period.

b. Considerations Concerning Previously Finalized ASC–11 Measure Requirements Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2022 OPPS/ASC proposed rule (86 FR 42272), we stated that it would be appropriate to require that ASCs report on ASC–11 for the CY 2023 reporting period/CY 2025 payment determination as ASCs have had the opportunity for several years to familiarize themselves with ASC–11, prepare to operationalize it, and to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. Many commenters expressed concern about making this measure mandatory due to the burden of reporting the measure and the impact this additional burden would have during the COVID–19 pandemic, stating that ASC–11 has not been mandatory and many facilities have not been practicing reporting it (86 FR 63886). In response to these comments, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a delay in the implementation of this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination (86 FR 63885 through 63887).

We now believe it is appropriate to suspend implementation of mandatory reporting and retain continue voluntary reporting for the ASC–11 measure and not require reporting starting with the CY 2027 payment determination. Since the publication of the CY 2022 OPPS/ASC final rule, interested parties have expressed concern about the reporting burden of this measure given the ongoing COVID–19 public health emergency (PHE). Interested parties have indicated that facilities remain impacted by the COVID–19 PHE and that the requirement to report ASC–11 would be burdensome due to national staffing and medical supply shortages coupled with unprecedented changes in patient case volumes. Due to the continued impact of the COVID–19 PHE, such as national staffing and medical supply shortages, we believe the two-year delay of mandatory reporting for this measure is no longer sufficient. Based on these factors and the feedback we received from interested parties, we believe it is appropriate to continue with voluntary reporting and delay mandatory reporting requirements for the ASC–11 measure until future rulemaking. Therefore, we propose to delay mandatory reporting of the ASC–11 measure beginning with CY 2025 reporting period/CY 2027 payment determination and maintain reporting for this measure as voluntary. ASCs would not be subject to a payment reduction for failing to report this measure during the voluntary reporting period; however, we strongly encourage ASCs to gain experience with the measure. We plan to continue to evaluate this policy moving forward. To be clear, there are no changes to reporting for the CY 2023 and CY 2024, during which the measure would remain voluntary.

As the ASC–11 measure uniquely requires cross-setting coordination among clinicians of different specialties (that is, surgeons and opthalmologists), we believe it appropriate to defer mandatory reporting at this time. We will consider mandatory reporting of ASC–11 after the national PHE declaration officially ends and we find it appropriate to do so given COVID–19 PHE impacts on national staffing and supply shortages. As we noted in the CY 2015 OPPS/ASC final rule, this measure addresses an area of care that is not adequately addressed in our current measure set and the measure serves to drive the coordination of care (79 FR 66984). We subsequently stated in the CY 2022 OPPS/ASC final rule with comment period that while the measure has been voluntary and available for reporting since the CY 2015 reporting period, a number of facilities have reported data consistently for this measure and those that have reported these data have done so consistently (86 FR 63886).

We invite public comment on this proposal.

4. ASCQR Program Quality Measure Set

a. Summary of Previously Finalized ASCQR Program Quality Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination and the CY 2024 Reporting Period/CY 2026 Payment Determination

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63875 through 63893) for the previously finalized ASCQR Program measure set for the CY 2023 program year and subsequent years.

Table 70 summarizes the previously finalized ASCQR Program measure set for the CY 2023 reporting period/CY 2025 payment determination and the CY 2024 reporting period/CY 2026 payment determination.

TABLE 70: ASCQR Program Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination and the CY 2024 Reporting Period/CY 2026 Payment Determination

ASC #	NQF #	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-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
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-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

† NQF endorsement was removed.

* The ASC-11 measure is voluntarily collected, as set forth in the CY 2015 OPPS/ASC final rule (79 FR 66984 through 66985).

b. Summary of the Proposed ASCQR Program Quality Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

Table 71 summarizes the previously finalized ASCQR Program measure set for the CY 2025 reporting period/CY 2027 payment determination and subsequent years as would be modified by the proposal described previously in this section of this proposed rule.

TABLE 71: Proposed ASCQR Program Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

ASC #	NQF #	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-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11*	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS - About Facilities and Staff
ASC-15b	None	OAS CAHPS - Communication About Procedure
ASC-15c	None	OAS CAHPS - Preparation for Discharge and Recovery
ASC-15d	None	OAS CAHPS - Overall Rating of Facility
ASC-15e	None	OAS CAHPS - Recommendation of Facility
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

† NQF endorsement was removed.
* The ASC-11 measure was previously finalized as mandatory for the CY 2025 program year as set forth in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63885 through 63887) and is being proposed as voluntary in this proposed rule.

5. ASCQR Program Measures and Topics for Future Consideration

a. Request for Comment: A Potential Future Specialty Centered Approach for the ASCQR Program

An overarching ASCQR Program goal is to have an up to date, comprehensive set of quality measures for widespread use to promote informed decision-making regarding clinical care and quality improvement efforts in the ASC setting. We recognize the clinician and clinician-group centered, specialized nature of care delivered in ASCs. We, therefore, seek comment on a potential future direction of quality reporting under the ASCQR Program that would allow quality-related data for ASCs to be reported on a customizable measure set that more accurately reflects the care delivered in this setting and accounts for the services provided by individual facilities. ASC services for Medicare beneficiaries are concentrated in a limited number of procedures. Because of this, there could be a set of measures related to different specialties, for example, ophthalmology, from which ASCs could choose a specified number, but individualized combination of measures. Another option could include the creation of specific specialized tracks which would standardize quality measures within a specialty area. Such a reporting structure could benefit ASCs by allowing them to focus on practice-specific measures on a specialty or multispecialty basis; patients and other interested parties could benefit through the provision of more relevant information on quality and safety within ASCs.

Specialty Centered Quality Reporting Under the Merit-Based Incentive Payment System (MIPS) [200]

The Merit-Based Incentive Payment System adjusts Medicare Part B payment to a clinician based on the clinician's prior performance on four performance categories.[201] The four performance categories on which clinicians are scored are quality, cost, improvement activities (IA), and Promoting Interoperability.[202] Under MIPS, CMS has established measure and activity inventories from which clinicians may select measures and activities to report and complete, respectively.[203] While the Traditional MIPS program is being phased out over time,[204] [205] we nonetheless believe that the quality performance category of the program provides an example of a specialty centered approach to quality reporting that is relevant to ASCs as clinically specialized facilities. We believe that quality reporting for ASCs would benefit from measures that:

- Consist of limited, connected, and complementary sets of measures and related activities that are meaningful to clinicians;
- Include measures and activities resulting in comparative performance data that are valuable to patients and caregivers in evaluating clinician performance and making choices about their care;

[200] Centers for Medicare & Medicaid Services. Quality Payment Program Overview. Available at: *https://qpp.cms.gov/about/qpp-overview.*

[201] *See* Social Security Act section 1848(q).

[202] *See id.* Section 1848(q)(2)(A)(i) and (iii).

[203] *See id.* Section 1848(q)(2)(D); *see also* 42 CFR 414.1355(a).

[204] CY 2022 Physician Fee Schedule final rule (86 FR 65376).

[205] Centers for Medicare & Medicaid Services. MIPS Value Pathways. Available at: *https://qpp.cms.gov/mips/mips-value-pathways.*

• Promote subgroup reporting that comprehensively reflects the services provided by multispecialty groups;

• Include measures selected using the Meaningful Measures [206] approach and, wherever possible, include the patient voice;

b. Solicitation of Comments on a Potential Future Specialty Centered Approach for the ASCQR Program

We request comment on the following questions for the ASCQR Program:

• Is the general concept of quality reporting by specialty feasible and desirable for ASCs participating in the ASCQR Program?

• Were we to adopt a specialty centered approach to quality measure reporting for the ASCQR Program, should CMS require that ASCs report a subset of quality measures that apply broadly to all ASCs? An example of potential broadly applicable measures for ASCs based on CY 2022 performance year MIPS quality measures [207] can be found in Table 73.

• Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, what would be the appropriate number and type of measures that ASCs should be required to report? Are there minimum and maximum numbers of measures required for ASCs that provide meaningful information while not being overly burdensome? What is the preferred balance of required quality measures that apply broadly to all ASCs and quality measures that apply to a particular area of specialization?

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[206] Centers for Medicare & Medicaid Services. Meaningful Measures Hub. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[207] Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: *https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022.*

TABLE 73: Potential Broadly Applicable ASCQR Program MIPS Quality Measures

MIPS MEASURE NAME	TYPE	SUMMARY OF MEASURE
Advance Care Plan	Process	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Anesthesiology Smoking Abstinence	Intermediate Outcome	The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.
CAHPS for MIPs Clinician/Group Survey	Patient Engagement Experience	Similar measure currently in ASCQR measure set (ASC-15 a-e).
Closing the Referral Loop: Receipt of Specialist Report	Process	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Documentation of Current Medications in the Medical Record	Process	Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Multimodal Pain Management	Process	Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.
Patient-Centered Surgical Risk Assessment and Communication	Process	Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.
Perioperative Temperature Management	Outcome	Currently in ASCQR measure set as Normothermia (ASC-13).

Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy	Process	Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.
Surgical Site Infection (SSI)	Outcome	Percentage of patients aged 18 years and older who had a surgical site infection (SSI).
Unplanned Hospital Readmission within 30 Days of Principal Procedure	Outcome	Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure (similar to ASC-17 and ASC-18).
Unplanned Reoperation within the 30 Day Postoperative Period	Outcome	Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.
Use of High-Risk Medications in Older Adults	Process	Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.

- Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, which area(s) of specialization would benefit from such an approach and which would not?
- Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, should CMS define a set of measures for particular areas of specialization (for example, ophthalmology) or should measures be self-selected for individual facilities from selected categories, especially given that an ASC may be multi-specialty?

We have considered several potential measure sets for the ASC setting based on CY 2022 performance year MIPS quality measures.[208] An example of an ophthalmology measure set using quality measures based on CY 2022 performance year MIPS quality measures [209] can be found in Table 73. An example of a gastroenterology measure set can be found in Table 75. We welcome comment on these specific examples as well as comment on potential future measure sets for other specialization areas.

- Were we to adopt a specialty centered approach for quality measure reporting under the ASCQR Program, should ASCs be required to report all measures in such a measure set, or should they be permitted to select a minimum number of measures from their selected measure set?
- Were we to adopt a specialty centered approach for quality measure reporting system under the ASCQR Program, what measures, if any, from the current ASCQR Program measure set should be retained and incorporated in such an approach?

[208] Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: *https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022.*

[209] Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: *https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022.*

TABLE 74: Example Ophthalmology ASCQR Program MVP Measures

MEASURE NAME	TYPE	SUMMARY OF MEASURE
Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery	Outcome	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.
Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery	Outcome	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.
Cataract Surgery: Difference Between Planned and Final Refraction	Outcome	Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.
Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery	Outcome	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Patient Reported Outcome	Similar measure currently in ASCQR measure set (ASC-11).
Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery	Patient Engagement Experience	Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.

TABLE 75: Example Gastroenterology ASCQR Program MVP Measures

MEASURE NAME	TYPE	SUMMARY OF MEASURE
Age Appropriate Screening Colonoscopy	Efficiency	The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.
Anastomotic Leak Intervention	Outcome	Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.
Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Process	Similar measure currently in ASCQR measure set (ASC-9).
Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Process	Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.
Photodocumentation of Cecal Intubation	Claims	The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.

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c. Request for Comment: Potential Future Reimplementation of ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC–7) Measure or Other Volume Indicator

(1) Background

ASC services for Medicare beneficiaries are concentrated in a limited number of procedures. Medicare covers surgical procedures represented in about 3,500 Healthcare Common Procedure Coding System (HCPCS) codes under the ASC payment system; however, ASC volume for services covered under Medicare is concentrated in a relatively small number of HCPCS codes. In 2019, for example, 29 HCPCS codes accounted for 75 percent of the ASC volume for surgical services provided to Medicare beneficiaries.[210]

Although ASCs perform procedures under a smaller and more specialized subset of HCPCS codes, the volume within these services continues to increase. Hospital care has been gradually shifting from inpatient to outpatient settings, and since 1983, inpatient stays per capita have fallen by 31 percent.[211] From 2014 to 2018, the volume of ASC services delivered per Medicare Part B Fee-for-Service (FFS) beneficiary increased by 2.1 percent.[212] During the same time period, the number of Part B FFS beneficiaries who received ASC services increased on average by 1.4 percent annually.[213] Research indicates that volume in ASCs will continue to grow, with some estimates projecting a 25 percent increase in patients between 2019 and 2029.[214]

Volume has a long history as a quality metric, however, quality measurement efforts had moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes.[215] More recent studies suggest that while larger facility surgical procedure volume does not alone lead to better outcomes, it may be associated with better outcomes due to having characteristics that improve care (for example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications), making volume an important component of quality.[216] The

[210] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/*.

[211] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf*.

[212] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/*.

[213] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/*.

[214] Sg2. Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. June 4, 2021. Available at: *https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/*.

[215] Jha AK. Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015.

[216] Auerbach AD et al. The Relationship between Case-Volume, Care Quality, and Outcomes of Complex Cancer Surgery. Journal of the American

ASCQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but did so previously. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74507 through 74509) where we adopted the ASC Facility Volume Data on Selected Procedures measure (ASC–7) beginning with the CY 2013 reporting period/CY 2015 payment determination. This structural measure of facility capacity collected surgical procedure volume data on six categories of procedures frequently performed in the ASC setting: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary (76 FR 74507). We adopted ASC–7 based on evidence that the volume of surgical procedures, and particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality. We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74507).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59449 and 59450), we removed ASC–7. We stated our belief at that time that measures on specific procedure types would provide patients with more valuable ASC quality of care information as these types of measures are more strongly associated with desired patient outcomes. Based on this belief, we removed the ASC–7 measure under 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. At the time, some commenters supported the proposal to remove the ASC–7 measure and agreed with CMS's rationale that the measure does not add value, however, some commenters opposed this proposal (82 FR 59449). Commenters that opposed removal of the ASC–7 measure emphasized the data's usefulness for comparative research, outcomes research, immediate consumer value, and strategic planning. Some of these commenters also expressed concerns that nonavailability of these data would interfere with the acceptance of ASC-based procedures also noting that the measure is not overly burdensome (82 FR 59449).

We are considering reimplementing the ASC–7 measure or another volume measure because, in addition to being an important component of quality, the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures.

Over the past few decades, innovations in the health care system have driven the migration of procedures from the inpatient setting to the outpatient setting. Forty-five percent of percutaneous coronary intervention (PCI) procedures shifted from the inpatient to outpatient setting from 2004 to 2014, and more than 70 percent of patients who undergo thoracoscopic surgery can be discharged on the day of surgery itself due to the use of innovative techniques and technologies available in the outpatient setting.[217] [218] Given the small number of HCPCS codes utilized by most ASCs, we also believe that patients may benefit from the public reporting of facility-level volume measure data that illuminates which procedures are performed across ASCs and provides the ability to track volume changes by facility and procedure category. Volume is an indicator for patients of which facilities are experienced with certain outpatient procedures.

ASC–7 was the only measure in the ASCQR Program measure set that captured facility-level volume within ASCs and volume for Medicare and non-Medicare patients. As a result of its removal, the ASCQR Program currently does not capture outpatient surgical procedure volume in ASCs.

Furthermore, we are considering the reintroduction of a facility-level volume measure to support potential future development of a pain management measure, as described in a request for comment in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63902 through 63904). When considering the need for a pain management measure, we analyzed volume data using the methodology established by ASC–7 to determine the proportion of ASC procedures performed for pain management. We found that pain management procedures were the third most common procedure in CYs 2019 and 2020 and concluded that a pain management measure would provide consumers with important quality of care information. Thus, a volume measure would provide Medicare beneficiaries and other interested parties information on numbers and proportions of procedures by category performed by individual facilities, including for ASC procedures related to pain management.

We note that the ASC–7 measure was adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74507 through 74509) and was not reviewed or endorsed by the Measure Applications Partnership (MAP), which first began its pre-rulemaking review of quality measures across Federal programs in February 2012 after the publication of the CY 2012 OPPS/ASC final rule with comment period in November 2011.[219] Therefore, for ASC–7 to be adopted in the ASCQR Program measure set, the measure would need to first undergo the pre-rulemaking process specified in section 1890A(a) of the Act.

(2) Solicitation of Comments on the Reimplementation of the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC–7) Measure or Other Volume Indicator in the ASCQR Program

We seek comment on the potential inclusion of a volume measure in the ASCQR Program, either by adopting the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC–7) measure or adopting another volume indicator. We also seek comment on what volume data ASCs currently collect and if it is feasible to submit this data to the ASCQR Program, to minimize the collection and reporting burden of an alternative, new volume measure. Additionally, we seek comment on an appropriate timeline for implementing and publicly reporting the measure data.

Specifically, we invite comment on the following:

- The usefulness of including a volume indicator in the ASCQR Program measure set and publicly reporting volume data;
- Input on the mechanism of volume data collection and submission, including anticipated barriers and solutions to data collection and submission;
- Considerations for designing a volume indicator to reduce collection burden and improve data accuracy;
- Potential reporting of volume by procedure type, instead of total surgical procedure volume data for select

College of Surgery. 2010;211(5):601–608. doi:10.1016/j.jamcollsurg.2010.07.006.

[217] Abrams KD, Balan-Cohen A, Durbha P. Growth in Outpatient Care: The role of quality and value incentives. Deloitte Insights. 2018. Available at: *https://www2.deloitte.com/us/en/insights/industry/health-care/outpatient-hospital-services-medicare-incentives-value-quality.html*.

[218] Chang AC, Yee J, Orringer MB, Iannettoni MD. Diagnostic thoracoscopic lung biopsy: an outpatient experience. The Annals of Thoracic Surgery. 2002;74:1942–7.

[219] Measure Applications Partnership. Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking Final Report. February 2012. Available at: *https://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx*.

categories, and which procedures would benefit from volume reporting; and

• The usefulness of Medicare versus non-Medicare reporting versus other or additional categories for reporting.

(3) Request for Comment: Interoperability Initiatives in ASCs

(a) Background

In 2009, under the Health Information Technology for Economic and Clinical Health Act (HITECH Act), financial incentives were authorized for hospitals and clinicians to adopt and meaningfully use certified electronic health record (EHR) technology.[220] We implemented these financial incentives by establishing the Medicare and Medicaid EHR Incentive Program (now known as the Promoting Interoperability Program), to encourage health care providers to adopt and meaningfully use certified EHR technology (CEHRT) and improve health care quality, efficiency, and patient safety.[221] The Promoting Interoperability Program also aims to improve care coordination, reduce costs, ensure privacy and security, improve population health, and engage patients and their caregivers in their own healthcare.

ASCs were not included in the HITECH Act and were ineligible for the financial incentives under the Promoting Interoperability Program. This differentiation may contribute to many ASCs continuing to utilize paper-based charts while other healthcare sectors have transitioned to digital records.[222] According to an EHR utilization survey conducted by the Ambulatory Surgical Center Association (ASCA), 54.6 percent of ASCs use an EHR in their facility, indicating that ASCs have a lower adoption rate compared to the 85.9 percent of office-based physicians reported by ONC.[223] Some EHR vendors have developed ASC-specific solutions; however, ASCs still face significant barriers to implementing EHRs as they can be expensive to implement and update, can require many staff hours for training, and may not offer ASCs a meaningful investment given the types of services provided and levels of patient follow-up required.[224]

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45460 through 45498) where we finalized changes to the Promoting Interoperability Program, and the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28576 through 28612) which proposes additional changes to the Promoting Interoperability Program. Currently, eligible hospitals and critical access hospitals (CAHs) are required to report on four scored objectives including electronic prescribing, health information exchange, provider to patient exchange, and public health and clinical data exchange, and must also attest to the following:[225]

• Security Risk Analysis measure.

• Safety Assurance Factors for EHR Resilience (SAFER) Guides measure.

• Actions to limit or restrict the compatibility or interoperability of CEHRT attestation.

• Office of the National Coordinator for Health Information Technology (ONC) Direct Review Attestation.

(b) Solicitation of Comments on Interoperability in ASCs

We seek comment to explore how ASCs are implementing tools in their facilities toward the goal of interoperability. We are considering a future shift in reporting from QualityNet to eCQMs to aid in delivering effective, safe, efficient, patient-centered, equitable, and timely care.[226] Transitioning to eCQMs would increase alignment across quality reporting programs such as the Hospital OQR Program, which adopted the STEMI eCQM in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63822 through 63875). We are interested in learning more about capabilities for reporting such measures in the future for the ASCQR Program. Generally, we seek input on: (a) Barriers to interoperability in the ASC setting; (b) the impact of health IT, including health IT, certified under the ONC Health IT Certification Program, on the efficiency and quality of health care services furnished in ASCs; and (c) the ability of ASCs to participate in interoperability or EHR-based quality improvement activities, including the adoption of electronic clinical quality measures (eCQMs).

Specifically, we invite comment on:

• What do ASCs perceive as the benefits or risks of implementing interoperability initiatives in their facilities?

• What improvements might be possible with the implementation of interoperability initiatives in ASCs, including EHR utilization (reduced delays, efficiencies, ability to benchmark, etc.)?

• Do ASCs see interoperability initiatives as non-essential or detrimental to their business practices?

Some clinicians practicing in ASCs may voluntarily participate in the MIPS Promoting Interoperability performance category, though they are not required to do so at this time.[227] We have considered several measures from the Promoting Interoperability Program and from the Traditional MIPS Promoting Interoperability measure set for the CY 2022 performance year that may be applicable for the ASC setting.[228] [229] An example of Promoting Interoperability measures potentially applicable for the ASC setting can be found in Table 76. We welcome comment on these specific measure examples, including whether ASCs believe these measures would be appropriate and feasible for use in ASCs.

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[220] Social Security Act section 1848(o)(2), amended by HITECH Act of 2009 section 4101 (February 2009).

[221] Centers for Medicare & Medicaid Services. CMS Finalizes Definition Of Meaningful Use Of Certified Electronic Health Records (EHR) Technology. July 2010. Available at: *https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-definition-meaningful-use-certified-electronic-health-records-ehr-technology*.

[222] Vail, T. Electronic Health Record Adoption is Essential for Outpatient Surgery. Managed Healthcare Executive. April 2021. Available at: *https://www.managedhealthcareexecutive.com/view/electronic-health-record-adoption-is-essential-for-outpatient-surgery*.

[223] Taira, A. ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus: The ASCA Journal. June 2021. Available at: *https://www.ascfocus.org/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-ascs*.

[224] Nelson, H. EHR Usability, User Satisfaction High in Ambulatory Surgery Centers. September 2021. Available at: *https://ehrintelligence.com/news/ehr-usability-user-satisfaction-high-in-ambulatory-surgery-centers*.

[225] Centers for Medicare & Medicaid Services. 2022 Medicare Promoting Interoperability Program Requirements. March 2022. Available at: *https://www.cms.gov/regulations-guidance/promoting-interoperability/2022-medicare-promoting-interoperability-program-requirements*.

[226] Centers for Medicare & Medicaid Services. 2022 Electronic Clinical Quality Measures Basics. March 2022. Available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures*.

[227] Centers for Medicare and Medicaid Services. Quality Payment Program Special Statuses. 2022. Available at: *https://qpp.cms.gov/mips/special-statuses*.

[228] Centers for Medicare and Medicaid Services. 2022 Medicare Promoting Interoperability Program Requirements. Available at: *https://www.cms.gov/regulations-guidance/promoting-interoperability/2022-medicare-promoting-interoperability-program-requirements*.

[229] Centers for Medicare and Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: *https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022*.

TABLE 76: Example Promoting Interoperability Measures Applicable to the ASCQR Program

MEASURE NAME		SUMMARY OF MEASURE
e-Prescribing		At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.
Health Information Exchange(HIE) Bi-Directional Exchange		The MIPS eligible clinician or group must establish the technical capacity and workflows to engage in bi-directional exchange via an HIE for all patients seen by the eligible clinician and for any patient record stored or maintained in their EHR.
Provide Patients Electronic Access to Their Health Information		For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician's certified electronic health record technology (CEHRT).
Query of the Prescription Drug Monitoring Program (PDMP)		For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.
Safe Use of Opioids – Concurrent Prescribing electronic clinical quality measure (eCQM)		Proportion of hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and

		benzodiazepine concurrently at discharge.
Security Risk Analysis		Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.
Support Electronic Referral Loops By Receiving and Reconciling Health Information		For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list.
Support Electronic Referral Loops By Sending Health Information		For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider - (1) creates a summary of care record using certified electronic health record technology (CEHRT); and (2) electronically exchanges the summary of care record.

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6. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for previously adopted ASCQR Program measures. These specifications are updated as we modify the ASCQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: *https://qualitynet.cms.gov/asc/specifications-manuals*. The policy on maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. We are not proposing any changes to these policies in this proposed rule.

7. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified at 42 CFR 416.315 (80 FR 70533). We are not proposing any changes to these policies in this proposed rule.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Official

We refer readers to the CYs 2014, 2016, and 2021 OPPS/ASC final rules with comment period (78 FR 75132 through 75133; 80 FR 70533; and 85 FR 86189, respectively) for the previously finalized QualityNet security official requirements, including requirements for setting up a QualityNet account and the associated timelines. These

procedural requirements are codified at 42 CFR 416.310(c)(1)(i). We are not proposing any changes to this policy in this proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule (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 (80 FR 70533 through 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 in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at 42 CFR 416.310.

b. Requirements for Claims-Based Measures

(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 (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 (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 note that the previously finalized data processing and collection period requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

(2) Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59472) (and the previous rulemakings cited therein), 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 also refer readers to section XVI.D.1.b. of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63904 through 63905), where we finalized that our policies for minimum threshold, minimum case volume, and data completeness requirements apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

(3) Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138) for a complete summary of the data processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program at 42 CFR 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously adopted measures:

- ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

We are not proposing any changes to these policies in this proposed rule.

c. Requirements for Data Submitted via an Online Data Submission Tool

(1) Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59473) (and the previous rulemakings cited therein) 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 Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal) to host our CMS online data submission tool, available by securely logging in at: *https://hqr.cms.gov/hqrng/login*. We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at 42 CFR 416.310(c)(1)(i). We are not proposing any changes to these policies in this proposed rule.

The following previously finalized measures require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;
- ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery;
- ASC–13: Normothermia Outcome; and
- ASC–14: Unplanned Anterior Vitrectomy.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63883 through 63885), we finalized our proposal to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination for the following four measures:

- ASC–1: Patient Burn;
- ASC–2: Patient Fall;
- ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC–4: All-Cause Hospital Transfer/Admission.

Measure data for these measures would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). We are not proposing any changes to these policies in this proposed rule.

(2) Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS- online data submission tool (specifically, the CDC's National Healthcare Safety Network (NHSN) website). We codified our existing policies regarding the data collection 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). While we did not finalize any changes to those policies in the CY 2022 OPPS/ASC final rule (86 FR 63875 through 63883), we did finalize policies specific to the COVID–19 Vaccination Coverage Among Health Care Personnel measure (ASC–20), for which data will be submitted via the CDC NHSN website. We are not proposing any changes to these policies in this proposed rule.

e. ASCQR Program Data Submission Deadlines

We refer readers to the CY 2021 OPPS/ASC final rule with comment

period (85 FR 86191) for a detailed discussion of our data submission deadlines policy, which we codified at 42 CFR 416.310(f). We are not proposing any changes to this policy in this proposed rule.

f. Review and Corrections Period for Measure Data Submitted to the ASCQR Program

Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191 through 86192) for a detailed discussion of our review and corrections period policy, which we codified at 42 CFR 416.310(c)(1)(iii). We are not proposing any changes to this policy in this proposed rule.

g. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We are not proposing any changes to this policy in this proposed rule.

h. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's extraordinary circumstance exceptions (ECE) requests policy. We are not proposing any changes to this policy in this proposed rule.

E. Proposed Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding 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 are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2022, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system 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 and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity 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 website): ''A2'', ''G2'', ''P2'', ''R2'' and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''G2'', ''J8'', ''P2'', ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS 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, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those 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 PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether

payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2022 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We propose the continuation of these policies for CY 2023.

XVI. Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background

1. Overview

We refer readers to section XIV of the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410) for a general overview of our Hospital Outpatient Quality Reporting (OQR) program and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Framework.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for other quality programs for outpatient settings including the Hospital OQR and the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

2. Statutory History of Quality Reporting for REHs

The Consolidated Appropriations Act (CAA), 2021, was signed into law in December 2020. In this legislation, Congress established a new Medicare provider type: Rural Emergency Hospitals (REHs). Section 125 of Division CC of the CAA added section 1861(kkk) to the Social Security Act (the Act). This section defines an REH as a facility that, in relevant part, was as of December 27, 2020 a Critical Access Hospital (CAH) or a subsection (d) hospital with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (defined in section 1886(d)(2)(D) of the Act) or was a subsection (d) hospital with not more than 50 beds that was treated as being in a rural area pursuant to section 1886(d)(8)(E) of the Act. Among other requirements, an REH must apply for enrollment in the Medicare program, provide emergency department services and observation care, and, at the election of the REH, provide certain services furnished on an outpatient basis, and not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)). Payment with respect to REH services may be made on or after January 1, 2023. Generally, a subsection (d) hospital is an acute care hospital—particularly one that receives payments under Medicare's inpatient prospective payment system (IPPS) when providing covered inpatient services to eligible beneficiaries. Similarly, a CAH is (as defined in section 1820 of the Act) a facility with no more than 25 inpatient beds, unless operating a psychiatric and/or a rehabilitation distinct part unit which may have up to 10 beds each.

We refer readers to section XIX of this proposed rule for our proposals with respect to payment policies, conditions of participation, and provider enrollment for REHs.

Under section 1861(kkk)(7) of the Act, as added by section 125 of Division CC of the CAA also requires the Secretary to establish quality measurement reporting requirements for REHs, which may include the use of a small number of claims-based measures or patient experience surveys. An REH must submit quality measure data to the Secretary, and the Secretary shall establish procedures to make the data available to the public on a CMS website.

3. Scope

The number of hospitals that convert to an REH and their characteristics may inform the selection of quality measures as we seek measures that are useable by REHs and that have sufficient numbers of REHs with sufficient volume of services to have meaningful measurement for individual facilities and, importantly, the public. REHs as defined by statute would be rural subsection (d) hospitals with not more than 50 beds and CAHs that convert in status to REHs. To estimate the number of facilities that are likely to consider conversion to an REH, one study [230] analyzed 1,673 rural hospitals on three criteria: (1) 3-years negative total margin; (2) average daily census of acute and swing beds being less than three; and (3) net patient revenue less than $20 million.[231] The analysis concluded that 68 would consider converting.[232] In contrast, an industry analysis based on estimated REH reimbursement and several financial assumptions [233] and four simulation methods, estimated that up to 600 CAHs would benefit from conversion to REH status.[234] Regardless of the exact number of facilities which convert, there may be quality measure challenges due to the low numbers of hospitals and volume of services provided by these facilities. We discuss possible approaches for addressing these low volume concerns in section XV.B.2.d of this proposed rule.

B. REHQR Program Quality Measures

1. Considerations in the Selection of REHQR Program Quality Measures

We seek to adopt a concise set of important, impactful, reliable, accurate, and clinically relevant measures for REHs that would inform consumer decision-making regarding care and further quality improvement efforts in the REH setting. In the CY 2022 OPPS/ASC proposed rule (86 FR 42285 through 42289), we sought comment

[230] Pink, G.H., et al., *How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)* 8 (July 2021), available at *https://www.shepscenter.unc.edu/download/23091/*.

[231] Ibid. at 5.

[232] Ibid. at 1.

[233] Estimated average facility payment, estimated outpatient fee schedule payment, estimated average skilled nursing facility payment rates by State, presence or loss of swing bed payments, and continuance or cessation of 340B eligibility.

[234] *https://www.claconnect.com/resources/articles/2022/a-path-forward-clas-simulations-on-rural-emergency-hospitaldesignation#:~:text=Depending%20on%20resolution%20of%20key,benefit%20from%20the%20new%20designation* (Accessed April 8, 2022).

through a Request for Information on various topics on REHs. Specifically, we sought input on the concerns of rural providers that should be taken into consideration by CMS in establishing quality measures and quality reporting requirements for REHs (86 FR 42288). We include issues raised and suggestions made from that Request for Information in this proposed rule as considerations for selecting measures for an REH quality reporting program.

a. Measure Endorsement

Under section 1861(kkk)(7)(C)(i) of the Act, unless the exception of subclause (ii) applies, a measure selected for the REHQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. Subclause (ii) provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, due to lack of an endorsed measure for a given facility setting, procedure, or other aspect of care, the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

b. Accountability and Quality

The overarching goals of this program, in line with other quality programs, are to improve the quality of care provided to beneficiaries, facilitate public transparency, and ensure accountability. We note that many subsection (d) hospitals and CAHs established on or before December 27, 2020 that are eligible for REH conversion are currently reporting outpatient quality data under the Hospital OQR Program and have publicly available data. We note that while such reporting is required for subsection (d) hospitals in order to avoid a payment penalty under the Hospital OQR Program, data submission and public reporting is voluntary for CAHs. We intend to adopt measures for the REHQR Program that are useful for REHs for their quality improvement efforts, but it is vital that measure information be of sufficient volume to meet case thresholds for facility level public reporting. See Tables 76 and 77 of this proposed rule for the current number of facilities and their current public reporting of Hospital OQR Program measure data as of January 2022 as well as the most recent data available for certain measures that have been removed from the OQR Program, but that may have continued relevance for an REHQR Program. The Medicare Beneficiary Quality Improvement Project (MBQIP) under the Medicare Rural Hospital Flexibility (Flex) program of the Health Resources and Services Administration utilizes outpatient quality data voluntarily reported by CAHs through the Hospital OQR Program. We note that per the 2020 MBQIP Quality Measures annual report, 1,353 CAHs (that is 86.5 percent of those eligible) reported data for at least one OQR measure,[235] which is greater than the number of facilities having data displayed Table 77 due to the low reporting volume exclusion limitation of Care Compare, indicating a greater capacity for these facilities to report on certain Hospital OQR measures.[236] Table 76 reflects data for reporting by rurally located subsection (d) hospitals with not more than 50 beds, and Table 77 reflects data for reporting by CAHs for the most recent Care Compare results available. These analyses present a starting place for assessing the extent of quality reporting by CAHs and small, rural hospitals for current or relatively recent measures with sufficient data for public reporting that could be considered for an REHQR Program.

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TABLE 76: Rural* subsection (d) hospitals with not more than 50 beds Publicly Reporting Selected Hospital Outpatient Measures (Current and those Previously Removed)**

Measure Number	Measure Title	Number Reporting With Measure Displayed on Care Compare	Percent Reporting
Hospital OQR measures on Care Compare, January 2022			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures; total of 191 hospitals	188	
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	4	2.13%
OP-3b	Median Time to Transfer to Another Facility for Acute Coronary Intervention	6	3.19%
OP-8	MRI Lumbar Spine for Low Back Pain	4	2.13%

[235] *https://www.flexmonitoring.org/sites/flexmonitoring.umn.edu/files/media/PA_Annual%20Report_2020.pdf* (Accessed June 5, 2022).

[236] *https://www.hrsa.gov/rural-health/grants/rural-hospitals/medicare-benificiary-quality-improvement (Accessed June 3, 2022).*

OP-10	Abdomen CT Use of Contrast Material	124	65.96%
OP-13	Outpatients who got cardiac imaging stress tests before low-risk outpatient surgery	27	14.36%
OP-18b	Average (median) time patients spent in the emergency department before leaving from the visit	152	80.85%
OP-18c	Average (median) time patients spent in the emergency department before leaving from the visit-Psychiatric/Mental Health Patients	92	48.94%
OP-22	Left before being seen	145	77.13%
OP-23	Head CT results	13	6.91%
OP-29	Endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk	109	57.98%
OP-31	Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	2	1.06%
OP-32	Rate of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies)	123	65.43%
OP-35-ADM	Rate of inpatient admissions for patients receiving outpatient chemotherapy	23	12.23%
OP-35-ED	Rate of emergency department (ED) visits for patients receiving outpatient chemotherapy	23	12.23%
OP-36	Ratio of unplanned hospital visits after hospital outpatient surgery	57	30.32%
	No OQR Measures Reported	8	4.26%
Hospital OQR measures on Care Compare, January 2021			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported measures	177	
OP-33	External Beam Radiotherapy for Bone Metastases	5	2.82%
Hospital OQR measures on Care Compare, January 2020			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures	175	
OP-5	Median Time to ECG	131	74.86%
OP-9	Mammography Follow-up Rates	121	69.14%
OP-11	Thorax CT Use of Contrast Material	118	67.43%
OP-14	Outpatients with brain CT scans who got a sinus CT scan at the same time	66	37.71%
OP-30	Endoscopy/polyp surveillance: colonoscopy interval for patients with a history of adenomatous polyps	110	62.86%
Hospital OQR measures on Care Compare, January 2018			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures	174	
OP-4	Aspirin at Arrival	130	74.71%
OP-20	Door to diagnostic evaluation	144	82.76%

Data sources: Hospital Compare data updated in January 2018, January 2020, January 2021, and January 2022, CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022, and QIO Program Resource System (PRS).
Hospitals are considered eligible to report on Hospital Compare when having a Medicare accept date prior to the latest measure end date and are identified as open as of PRS access date.
*Rural/urban location is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural to limit the analysis to areas currently viewed as rural.
** A hospital is considered reporting for this data presentation if it has a Hospital OQR measure published on Care Compare; a hospital may report data to CMS, but not have data published on Care Compare due to not meeting case number requirements

TABLE 77: Critical Access Hospitals Publicly Reported Selected Hospital Outpatient Measures*

Measure Number	Measure Tile	Number Reporting With Measure Displayed on Care Compare	Percent of Reporting CAHs With Measure Results Displayed
Hospital OQR measures on Care Compare, January 2022			
	CAHs with publicly reported measures; total number 1,354 plus 5 new CAHs not yet with data	1,354	
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	5	0.37%
OP-3b	Median Time to Transfer to Another Facility for Acute Coronary Intervention	17	1.26%
OP-8	MRI Lumbar Spine for Low Back Pain	2	0.15%
OP-10	Abdomen CT Use of Contrast Material	838	61.89%
OP-13	Outpatients who got cardiac imaging stress tests before low-risk outpatient surgery	79	5.83%
OP-18b	Average (median) time patients spent in the emergency department before leaving from the visit	1,085	80.13%
OP-18c	Average (median) time patients spent in the emergency department before leaving from the visit- Psychiatric/Mental Health Patients	543	40.10%
OP-22	Left before being seen	775	57.24%
OP-23	Head CT results	51	3.77%
OP-29	Endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk	207	15.29%
OP-31	Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	7	0.52%
OP-32	Rate of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies)	625	46.16%
OP-35-ADM	Rate of inpatient admissions for patients receiving outpatient chemotherapy	84	6.20%
OP-35-ED	Rate of emergency department (ED) visits for patients receiving outpatient chemotherapy	84	6.20%
OP-36	Ratio of unplanned hospital visits after hospital outpatient surgery	94	6.94%
Hospital OQR measures on Care Compare, January 2021			
	CAHs with publicly reported selected measures	1,347	
OP-33	External Beam Radiotherapy for Bone Metastases	6	0.45%
Hospital OQR measures on Care Compare, January 2020			
	CAHs with publicly reported selected measures	1,343	

OP-5	Median Time to ECG	863	64.26%
OP-9	Mammography Follow-up Rates	904	67.31%
OP-11	Thorax CT Use of Contrast Material	818	60.91%
OP-14	Outpatients with brain CT scans who got a sinus CT scan at the same time	615	45.79%
OP-30	Endoscopy/polyp surveillance: colonoscopy interval for patients with a history of adenomatous polyps	188	14.00%
Hospital OQR measures on Care Compare, January 2018			
	CAHs with publicly reported measures	1,325	
OP-4	Aspirin at Arrival	612	46.19%
OP-20	Door to diagnostic eval	726	54.79%

Data sources: Hospital Compare data updated in January 2018, January 2020, January 2021, and January 2022, CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022, and QIO Program Resource System (PRS).
Hospitals are considered eligible to report on Hospital Compare when having a Medicare accept date prior to the latest measure end date and are identified as open as of PRS access date.
*Rural/urban location is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural to limit the analysis to areas currently viewed as rural.
** A hospital is considered reporting for this data presentation if it has a Hospital OQR measure published on Care Compare; a hospital may report data to CMS, but not have data published on Care Compare due to not meeting case number requirements

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c. Burden

We recognize REHs will be smaller hospitals that have limited resources compared with larger hospitals in metropolitan areas.[237] Certain measures, particularly those that are chart-abstracted, may be more burdensome than other measures to report. Rural facilities often experience shortage of non-clinical staff to perform certain administrative duties, such as collecting and reporting quality measures.[238] For the REHQR Program, we intend to seek balance between the costs associated with reporting data and the benefits of ensuring safety and quality of care through measurement and public reporting. We recognize these challenges faced by the hospitals eligible to convert to REH status may increase reporting burden and may necessitate limiting the number of quality measures in use for the REH quality reporting program to facilitate success. There are several avenues we can consider for limiting this burden (that is, reducing the costs associated with reporting the data required for quality measurement) including: (1) use of Medicare claims-based measures; and (2) use digital quality measures in place of chart-abstraction. In addition, we believe that, to the extent possible, existing quality measures should align across Medicare, Medicaid, and other payers to minimize reporting burden. The Hospital Promoting Interoperability Program, which includes a requirement to report certain eCQMs, shows that of 1,308 CAHs, 1,066 (81.5 percent) met eCQM reporting requirements for the first quarter of 2022. This indicates a relatively high level of reporting capability for eCQMs by a hospital type that tends to be smaller and more likely to be situated in more rural areas.

d. Rural Relevance

The measures included in an REH quality program should reflect the types of services and care delivered most frequently in that setting, along with areas of care where there may be inappropriate variation or potential quality of care challenges.[239] For example, an REH may provide ambulatory and outpatient procedures with supporting diagnostic services such as laboratory tests and x-rays, and be considered a low-volume emergency department (ED). Larger variation between these smaller providers due to lower case volumes could allow some topped out measures that are no longer meaningful for larger or urban hospitals to be utilized for rural hospital quality reporting. More specifically, topped-out measures could be re-purposed for reporting the quality of their rural counterparts, which have not achieved the level of success in these measures as often as a result of low-case volumes. In addition, we believe that it may be appropriate to include some measures that would apply to all REHs, for example, measures that are tailored to ED and observation services, while instituting additional applicable measures for REHs that choose to provide additional outpatient services.

e. Low Service and Patient Volume

Section 1861(kkk)(7)(C)(iii) of the Act specifies that the Secretary shall, in the selection of measures, take into consideration ways to account for rural emergency hospitals that lack sufficient case volume to ensure that the performance rates for such measures are reliable. Effective quality measurement requires a sufficiently large patient number or services volume to account for level of measure variability. This ensures that the quality measure has the necessary reliability of an individual facility's information as well as to detect

[237] American Hospital Association, *Rural Report 2019: Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, Affordable Care* 3 (February 2019), available at *https://www.aha.org/system/files/2019-02/rural-report-2019.pdf.*

[238] Ibid at 6 & 7.

[239] National Quality Forum, *Measure Application Partnership: A Core Set of Rural Relevant Measures and Measuring and Improving Access to Care, 2018 Recommendations from the MAP Rural Health Workgroup, Final Report* 24 & 26 (August 2018), available at *https://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx.*

meaningful distinctions between facilities. Possible approaches to quality measurement where low volume is expected are discussed in section XV.B.2.d of this proposed rule.

f. Health Equity

We believe methods to examine disparities in health care delivery and quality measurement should include stratified results using, for example, patient dual eligibility and other social vulnerability factors as well as patient demographic information to capture the breadth of social determinants of health in rural areas.[240] Other factors or indicators to consider for equity measurement include access to care, disability and functional status, veteran status, health literacy, language preference, race and ethnicity, tribal membership, sexual orientation and gender identity, and religious minority status. These demographic characteristics and social determinants of health can enable a more comprehensive assessment of health equity to further identify and develop actionable strategies, including the selection of quality measures and quality improvement, to promote health equity.

One approach being considered to measure equity across our programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables. The Request for Information (RFI) included in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 19415), titled ''Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs'' describes key considerations across all CMS quality programs, including the Hospital OQR Program, when advancing the use of measure stratification to address health care disparities and advance health equity across our programs.

We refer readers to the full RFI in the FY 2023 IPPS/LTCH PPS proposed rule for details on these considerations (87 FR 19415); for comments and feedback on the application of these principles to a quality reporting program for REHs, please respond to this RFI.

We discuss possible measures of equity for use in a REHQR Program in section XV.B.3 of this proposed rule.

2. Request for Comment on Potential Measures for an REHQR Program

a. Selected Hospital OQR Program Measures Recommended by the National Advisory Committee on Rural Health and Human Services for the REHQR Program

The National Advisory Committee on Rural Health and Human Services for the REHQR Program's measure recommendations drew from measures that were currently being reported or were recently reported under CMS' Hospital OQR Program or HRSA's MBQIP.[241] In this proposed rule, we request comment on a selection of measures from this report as we review measures for potential future inclusion in the REHQR Program. We seek to better understand how these measures may help achieve our goal of selecting measures for the REHQR Program that focus on REH areas of care, especially ED care. Measures with an OP designation represent current or past Hospital OQR measures; measure specifications are contained in program specifications manuals (current and past back to CY 2013) available on the QualityNet website.[242]

(1) OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

This chart-abstracted process measure calculates the percentage of ED acute myocardial AMI patients with ST-segment elevation on the electrocardiogram (ECG) closest to arrival time receiving fibrinolytic therapy during the ED stay and having a time from ED arrival to fibrinolysis of 30 minutes or less. The measure is calculated using chart-abstracted data, on a rolling, quarterly basis and is publicly reported, in aggregate, for one calendar year. We have publicly reported this measure under the Hospital OQR Program since 2012. In the CY 2022 OPP/ASC final rule (86 FR 63823 through 63824), OP–2 was finalized for removal from the Hospital OQR Program beginning with the CY 2023 reporting period/CY 2025 payment determination, with planned replacement with an electronic clinical quality measure (eCQM) that combines this measure with OP–3 Median Time to Transfer to Another Facility for Acute Coronary Intervention, the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM (86 FR 63823 through 63824). The adoption of the STEMI eCQM and the measure calculation method for the Hospital OQR Program was finalized in this same final rule (86 FR 63837 through 63840). The current level of rurally located subsection (d) hospitals with not more than 50 beds (4 total) and CAHs (5 total) with data publicly displayed on Care Compare for this measure is relatively low (see Table 77 and 77 of this proposed rule). However, the MBQIP (which utilizes data reported through the Hospital OQR Program) reported that about 71 percent of CAHs reported at least one case for the OP–2 measure.

(2) OP–3: Median Time To Transfer to Another Facility for Acute Coronary Intervention

Time to transfer to receiving facilities delays time to reperfusion in patients with ST segment elevation myocardial infarction (STEMI). There are multiple, critical system practices that minimize transfer time to receiving centers; however, two characteristics of the sending facility have been noted as most important: performance of a prehospital electrocardiogram and having established transfer protocols.[243] The use of time-to-transfer quality measures in rural areas may raise equity concerns as the geographic isolation of many rural facilities and the lack of uniformity in geographic isolation may be outside the control of the facilities measured.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63458), OP–3 was finalized for removal from the Hospital OQR Program beginning with the CY 2023 reporting period/CY 2025 payment determination due to availability of a more broadly applicable measure that captures the OP–2 and OP–3 measure populations and expand beyond these populations to comprehensively measure the timeliness and appropriateness of STEMI care, with planned replacement of these measures by an eCQM. The current level of subsection (d) hospitals and CAHs with data publicly displayed on Care Compare for this chart-abstracted measure is relatively low possibly due to case numbers below the threshold to allow the data to be publicly reported (see Tables 76 and 77 of this proposed rule). About 70 percent of CAHs reported at least one case for this measure through the MBQIP program.

We invite public comment on potential future adoption of OP–3 and

[240] Agency for Healthcare Research and Quality, *Chartbook on Rural Healthcare: National Healthcare Quality and Disparities Report* 8 &13–14 (November 2021) available at *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/2019-qdr-rural-chartbook.pdf.*

[241] *https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2021-rural-emergency-hospital-policy-brief.pdf* (Accessed April 8, 2022).

[242] *https://qualitynet.cms.gov/outpatient/specifications-manuals* (Accessed May 20, 2022).

[243] Mumma, BE, Williamson, C, Diercks, DB. Minimizing transfer time to an ST segment elevation myocardial infarction receiving center: Modified Delphi Consensus. Crit Pathw Cardiol 2014, Mar; 13(1):20–24.

its replacement STEMI eCQM for the REHQR Quality Reporting Program.

(3) OP–4: Aspirin on Arrival

This chart-abstracted process measure documents the percentage of ED acute myocardial infarction (AMI) patients or chest pain patients (with probable cardiac chest pain) without aspirin contraindications who received aspirin within 24 hours before ED arrival or prior to transfer at the facility level. The early use of aspirin in patients with AMI results in a significant reduction in adverse events and subsequent mortality. OP–4 was implemented into the Hospital OQR program in CY 2008 and removed for the CY 2020 payment determination and subsequent years due to performance being sufficiently high with little variation between providers (82 FR 52570).

While being topped out at the national level and no longer useful for larger or urban providers, this measure could be useful for smaller providers, including those that may convert to REH status, due to sufficient variation between individual facilities to permit the measurement of differences. An analysis (Table 78) of the last publicly reported OP–4 data for small rurally located hospitals and CAHs shows such variation between facilities (both urban and rural) with the lower 10th percentile. The analysis found providers with much lower percentages of proper aspirin administration across urban/rural areas for CAHs and subsection (d) hospital types and slightly higher variation as measured by standard deviation, indicating room for improvement. We note that some CAHs, while considered rural for Medicare payment purposes, are situated in areas that can be considered urban. The analysis in Table 78 is only to examine for variations by urban versus rural setting. This measure was retired and NQF endorsement removed from the Cardiovascular Project in 2013 with subsequent removal from the Hospital OQR Program for the CY 2018 reporting period/CY 2020 payment determination. A similar measure, Emergency Medicine: Aspirin at Arrival for Acute Myocardial Infarction (AMI) was also retired and NQF endorsement removed in 2017 (82 FR 59439).

TABLE 78: Urban, Rural subsection (d) Hospitals with not more than 50 beds and CAHs Reporting* OP-4: Aspirin on Arrival Reporting (Care Compare 2018)**

Hospital Type	Rural/ Urban	N	Mean	Std Dev	Min	10th PCTL	25th PCTL	Median	75th PCTL	90th PCTL	Max
CAH	Rural	463	94.78	6.65	57	86	92	97	100	100	100
CAH	Urban	149	95.17	6.08	65	87	93	98	100	100	100
subsection (d) hospital	Rural	130	93.98	6.92	63	86.5	92	96	99	100	100
subsection (d) hospital	Urban	87	94.26	5.81	70	87	91	96	99	100	100

* Hospitals are considered reporting if measure data are published on Care Compare. Rural/urban location is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural.

**The January 2018 release of Care Compare contained the final publicly available data for OP-4.

(4) OP–18: Median Time From ED Arrival to ED Departure for Discharged ED Patients

Care provided in the ED will be a focus of REH services and we seek measures that assess the quality of care in this setting. OP–18 is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED or ED throughput time. Improving ED throughput times is important for alleviating overcrowding and reducing wait times; conditions which can lead to potential safety events and patient dissatisfaction.[244] OP–18 is a current measure for the Hospital OQR Program and reporting for this measure by hospitals eligible to convert to REH status is relatively high (see Table 76 of this proposed rule). Note that the OP–18 measure is calculated for varying types of patients: the OP–18b measure excludes psychiatric/mental health and transferred patients; alternatively, the OP–18c measure includes information only for psychiatric/mental health patients.

[244] *https://www.healthcatalyst.com/wp-content/uploads/2021/05/Data-Driven-Operations-Improve-ED-Efficiency.pdf.*

(5) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional

This chart-abstracted, ED measure measures the mean time between patient presentation to the ED and the first moment the patient is seen by a qualified medical person for patient evaluation and management. As REH's main area of care and associated services provided will be related to their ED, and emergency services can be time-sensitive, this measure provides tailored accountability for this setting type. OP–20 was removed from the Hospital OQR Program in the CY 2018 OPPS/ASC final rule beginning with CY 2020 payment

determinations (82 FR 52570). During regular measure maintenance, specific concerns were raised by a Technical Expert Panel resulting in removal of this measure from the Hospital OQR Program due to measure performance or improvement not resulting in better patient outcome (82 FR 59431)). However, while some commenters agreed with this reasoning, other commenters expressed concern that there are socioeconomic pressures that can vary by community that cause variation in performance on this measure, noted the value of this measure, and recommended that a refined version that stratifies by other factors related to measure performance, specifically mentioning hospital size which would be more effective in a specific setting (82 FR 59431). When required for the Hospital OQR Program, a significant number of hospitals eligible for REH conversion that had data publicly reported had sufficient case volumes to have publicly reported data for this measure; 70.69 percent (82) of hospitals and 51.93 percent (445) of CAHs that had any measure publicly reported indicating possible usefulness of this measure for REHs.

(6) OP–22: Left Without Being Seen

This structural measure for the ED setting is focused on reflecting staffing expertise and availability. OP–22 measures the percentage of patients who left the ED before being evaluated by a physician, advanced practice nurse (APN), or physician assistant (PA) and uses all-payer, administrative data (not Medicare claims data) to determine the measure's numerator and denominator populations. This measure is in the current Hospital OQR Program measure set with significant numbers of both hospitals and CAHs eligible for REH conversion that have publicly reported data for this measure.

We request comment on these selected Hospital OQR Program measures that were recommended by the National Advisory Committee on Rural Health and Human Services for their use in a REHQR Program.

b. Medicare Beneficiary Quality Improvement Project (MBQIP) Measure Recommended by the National Advisory Committee on Rural Health and Human Services for the REHQR Program

The MBQIP is a quality improvement activity under the Medicare Rural Hospital Flexibility (Flex) program. The MBQIP supports more than 1,350 CAHs in 45 states to improve quality of care. Measures included in the MBQIP that are also included in our selection of measures from those by the National Advisory Committee on Rural Health and Human Services for the REHQR Program (above) are OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival, OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention, OP–18: Median Time from ED Arrival to ED departure for Discharged ED Patients, and OP–22: Left Without Being Seen.

The Emergency Department Transfer Communications (EDTC) measure is a core measure in the MBQIP program for CAHs and was included in those measures recommended by the National Advisory Committee on Rural Health and Human Services for their use in a REHQR Program. The EDTC measure assesses how well key patient information is communicated from an ED to any health care facility. The measure is applicable to patients with a wide range of medical conditions (that is, acute myocardial infarction (AMI), heart failure, pneumonia, respiratory compromise, and trauma) and is relevant for both internal quality improvement purposes and external reporting to consumers and purchasers.[245] As REHs are expected to focus on triage and transfer, the adequate and timely sharing of information with the receiving site would be an important quality metric.

We request comment on the EDTC measure for use in a REHQR Program.

c. Other Current, Claims-Based Hospital OQR Quality Measures

Measures calculated using administrative data from Medicare claims and enrollment data limit provider burden and provide valuable information regarding Medicare beneficiary service utilization and care provision. The Hospital OQR Program has several established measures of this type that could be applicable to REHs. At this time, we are focusing on two current measures that have publicly reported data and that focus on services expected to be provided by hospitals eligible for REH conversion: OP–10 Abdomen Computed Tomography (CT)—Use of Contrast Material and OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

(1) OP–10: Abdomen Computed Tomography (CT)—Use of Contrast Material

This diagnostic imaging measure is based fully on Medicare fee-for-service (FFS) claims and enrollment data. It calculates the percentage of CT abdomen studies performed with and without contrast out of all CT abdomen studies performed (those without contrast, those with contrast, and those with both). A CT study performed with and without contrast doubles the radiation dose to patients, exposing them to the potential harmful side effects of the contrast material itself.[246] Davis et al. (2020) showed that while rural facilities account for 32.2 percent of all facilities, they account for 46.0 percent of the outliers for the OP–10 measure. This indicates considerable variation and possible areas for targeted improvement.

(2) OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

This outcome measure is calculated fully using Medicare FFS claims and enrollment data, estimating a facility-level rate of risk standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare FFS patients aged 65 years and older. OP–32 captures and makes more visible to providers and patients all unplanned hospital visits following colonoscopy procedures. Under the Hospital OQR program, of the hospitals eligible for REH conversion that had sufficient case volumes to have publicly reported data for this measure, 65.43 percent (123) of hospitals and 46.16 percent (625) of CAHs had any publicly reported data. While the total numbers of hospitals with publicly reported OP–32 data is somewhat low, this could be an important measure for those REHs providing outpatient services and for patients seeking information regarding complications following this procedure. OP–32 was adopted in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66963) for the CY 2018 payment determination and subsequent years using CY 2016 data for the initial year's measure calculation.

d. Request for Comment on Additional Measurement Topics and for Suggested Measures for REH Quality Reporting

Our request for information in the CY 2022 OPPS/ASC proposed rule yielded suggested additional topics for quality measures appropriate to the REH setting. We request comment on the below additional topics and request suggestions for specific measures to assess the patient experience, outcome, and processes related to these topics. In

[245] *https://www.ruralcenter.org/resource-library/edtc-measure-data-reporting-resources* (Accessed May 12 2022).

[246] Davis M, McKiernan C, Lama, S, Parzynski C, Bruetman C, Venkatesh A. Trends in publicly reported quality measures of hospital imaging efficiency, 2011–2018. AJR: 215, July: 153–158), 2020.

addition, we request comment on other potential topics not listed that would be applicable to an REH quality reporting program.

(1) Telehealth

REHs can utilize telehealth and other remote service capacities in serving rural communities in their vicinity. Under the COVID–19 PHE, temporary measures to facilitate the provision and receipt of care through telehealth were federally implemented.[247] Additionally, section 301 of Division P of the Consolidated Appropriations Act (CAA), 2022 extended certain telehealth flexibilities for Medicare patients for 151 days after the official end of the Federal public health emergency (PHE).[248] The PHE was most recently extended on April 12, 2022, effective April 16, 2022, to July 15, 2022.[249] Section 301 of the CAA, 2022 permits certain Medicare beneficiaries to receive telehealth services from their home. This and other flexibilities will facilitate the use of telehealth for 151 days after the expiration of the PHE in rural areas.[250]

In addition, rural emergency telehealth services present unique opportunities for access to quality care in these often time-sensitive and geographically isolated cases. For instance, utilizing provider-to-provider telehealth or telemedicine support, such as in the case of e-consultation or tele-emergency care services, in a rural emergency department could allow for critical specialist knowledge transfer and reduce patient transfers and wait times.[251] This is particularly impactful in the face of rural facility or departmental closures which can leave gaps in healthcare service access and could contribute or lead to emergency service requirements, such as in the case of obstetric challenges.[252]

We seek public comment on potential future quality measures development to address quality of care using telehealth services in rural and rural emergency settings; as well as, on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render quality care services.

(2) Maternal Health

Nearly half of rural U.S. counties lack hospitals with basic capacity to provide emergency obstetric services. In New Mexico, for example, one-third of deaths during pregnancy and in the first year postpartum are from car accidents with increasing maternal mortality and morbidities in rural areas of the State.[253] Similarly, the Illinois Morbidity and Mortality Report identified 175 pregnancy-associated deaths that occurred during 2016–2017 and revealed that the number of pregnancy-associated deaths per 100,000 live births was higher in rural counties.[254] This report identified the greatest (33 percent) underlying cause of pregnancy-associated death in rural counties was attributed to ''other injuries'', most of which was the result of motor vehicle crashes, as opposed to 'all medical' (31 percent), drug overdose (21 percent), suicide (10 percent), or homicide (5 percent).[255] This was in contrast with the 4 percent to 10 percent of this category's attribution in the non-rural areas.[256]

REHs could provide valuable emergency care and other outpatient services for preserving and improving maternal health in rural areas, such as providing outpatient OB services in ''OB deserts''.[257] REHs could also leverage remote patient monitoring. This could include implementing telehealth systems to ensure engagement and timely notification and care among high-risk patients, while also reducing barriers to care, like distance and travel.[258] In addition, REHs could possibly fill gaps in the maternity care continuum, or play a critical role in a patient's emergency plan by being identified as their closest medical facility equipped to handle a maternal health emergency.[259]

We seek public comment on potential future quality measures for maternal health services in rural and rural emergency settings, and on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render quality maternal health care services.

(3) Mental Health

Rural populations are disproportionately affected by mental health concerns including substance use disorders.[260] [261] For example, suicide rates and drug overdose related deaths are especially on the rise among the rural population.[262] [263] Roughly 6.5 million individuals, or about one-fifth of the rural population, had a mental illness in 2019.[264] While rates of mental illness and substance use disorder between rural and urban areas are comparable, serious mental illness (SMI) was found to be 1.7 percent greater for rural adults 18 and older than their urban counterparts.[265] Contributing to this problem is the presence of contextual and cultural factors, such as stigma, isolation, and poverty, and the lack of access to trained and specialized mental health providers, with over 60 percent of rural Americans living within a designated shortage area.[266] There are also higher reported rates of prescription opioid misuse among rural residents, but

[247] *http://telehealth.hhs.gov* (Accessed April 8, 2022).

[248] Public Law 117–103.

[249] *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-12Apr2022.aspx* (Accessed May 12, 2022).

[250] *https://www.foley.com/en/insights/publications/2022/03/congress-extends-telehealth-flexibilities-7-things* (Accessed April 13, 2022).

[251] *https://telehealth.hhs.gov/providers/telehealth-for-emergency-departments/* (Accessed May 31, 2022).

[252] Centers for Medicare & Medicaid Services (CMS), *Advancing Rural Maternity Health Equity,* 10 (May 2022), available at *https://www.cms.gov/files/document/maternal-health-may-2022.pdf.*

[253] The Commonwealth Fund. Restoring Access to Maternity Care in Rural America. September 30, 2021. *https://www.commonwealthfund.org/publications/2021/sep/restoring-access-maternity-care-rural-america* (Accessed April 8, 2022).

[254] Illinois Department of Public Health, *Illinois Maternal Morbidity and Mortality Report, 2016–2017* 25 (April 2021), available at *https://dph.illinois.gov/content/dam/soi/en/web/idph/files/maternalmorbiditymortalityreport0421.pdf.*

[255] Ibid. at 28.

[256] Ibid. at 28.

[257] *https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/bridging-the-gaps-with-telehealth/* (Accessed May 31, 2022).

[258] *https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/telehealth-and-high-risk-pregnancy/* (Accessed May 31, 2022).

[259] *https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/preparing-patients-and-providers/* (Accessed May 31, 2022).

[260] White B.G. (2015 January 28). Rural America's Silent Housing Crisis. The Atlantic. Retrieved from: *https://www.theatlantic.com/business/archive/2015/01/rural-americas-silent-housing-crisis/384885.*

[261] Shawnda S. (2017 November). Rural Behavioral Health. Rural Health Research RECAP. Retrieved from: *https://www.ruralhealthresearch.org/assets/658-1990/rural-behavioral-health-recap.pdf.*

[262] Centers for Disease Control and Prevention. (2018 February 28). Drug Overdose in Rural America. Retrieved from: *https://www.cdc.gov/ruralhealth/drug-overdose/index.html.*

[263] Centers for Disease Control and Prevention. (2018 March 22). Suicide Policy Brief: Preventing Suicide in Rural America. Retrieved from: *https://www.cdc.gov/ruralhealth/suicide/policybrief.html.*

[264] Morales, D.A., Barksdale, C.L., & Beckel-Mitchener, A.C. (2020). A call to action to address rural mental health disparities. *Journal of clinical and translational science,* 4(5), 463–467. *https://doi.org/10.1017/cts.2020.42.*

[265] Neylon, K.A. (2020). Strategies for the Delivery of Behavioral Health Crisis Services in Rural and Frontier Areas of the U.S. Alexandria, VA: National Association of State Mental Health Program Directors.

[266] Morales, D.A., Barksdale, C.L., & Beckel-Mitchener, A.C. (2020). A call to action to address rural mental health disparities. *Journal of clinical and translational science, 4*(5), 463–467. *https://doi.org/10.1017/cts.2020.42.*

reduced availability of outpatient substance use treatment services, with nearly four times greater likelihood of availability in urban areas than in rural areas.[267]

These high rates of mental health and substance use issues, compounded by lack of access to treatment, underscores the need for an array of behavioral health crisis services in rural areas. REHs could fill this need by providing valuable emergency care and other outpatient services for patients experiencing mental health and substance use crises, and possibly bridging the gaps in the continuum of care. For example, REHs could use telehealth services to reduce care delays,[268] or offer teletherapies which can reduce stigma and privacy concerns.[269]

We seek public comment on potential future quality measures for behavioral health services in rural and rural emergency settings, and on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render quality behavioral health care services.

(4) ED Services

Emergency departments and the services provided in this setting are expected to be a focus of REHs. OP–18: Median Time from ED Arrival to ED departure for Discharged ED Patients, OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and OP–22: Left Without Being Seen, for example, all measure important aspects of ED care.

ED utilization is another important aspect of ED care and quality measures for Medicare Advantage plans as well as for Medicaid beneficiaries point to this. The Emergency Department Utilization (EDU) Health Effectiveness Data and Information Set (HEDIS) measure assesses ED utilization among Medicare Advantage (18 and older) beneficiaries through an observed-to-expected ratio.[270] For this measure, Medicare Advantage plans report observed rates of ED use and a predicted rate of ED use based on the health of their member population and factors.[271] Similarly, we recently sought stakeholder comments on a Medicaid measure under development, the All-Cause ED Utilization for Medicaid Beneficiaries measure.[272] This measure is defined as the number of all-cause ED visits per 1,000 beneficiary months among Medicaid beneficiaries aged 18 years and older with at least 10 months of enrollment.

A patient who returns for an unscheduled visit to the emergency department (ED) shortly after initial discharge (that is, within 2–30 days) is called a ''bounce-back.'' [273] ED bounce-backs are associated with ED facility and ED patient metrics, including quality of care, patient insurance status, patient age, ED overcrowding and patient satisfaction, or an unscheduled return visit. Measures for ED utilization, boarding, and unscheduled ED return visits (bounce-backs) could be useful quality metrics for the REH setting.

We seek public comment on potential future quality measures for emergency care services in rural and rural emergency settings, and on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render quality of care.

(5) Equity

Rural populations, among others, face historic and current disproportionate health impacts that have resulted in the higher prevalence, increased risk, and greater barriers to care for medical conditions.[274] The Hospital Commitment to Health Equity measure,[275] which we have proposed in the FY 2023 IPPS rule for the Hospital Inpatient Quality Reporting program, has five attestation-based questions that each represent a domain of commitment to health equity: strategic planning, data collection, data analysis, quality improvement, and leadership engagement. Additionally, a potential future measure for health equity could be an attestation-based structural measure of a disparities impact statement (DIS) or organizational pledge that outlines how infrastructure supports the delivery of care that is equitable for all patient populations could provide important information regarding organizational commitment to health equity.

We seek public comment on potential future quality measures for health equity in rural and rural emergency settings, and on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render equitable, quality of care.

e. Addressing Concerns Regarding Small Case Numbers

There are significant methodological challenges with measurement in rural and low-volume settings. Measure reliability and validity often hinge on having a sufficient volume of cases to ensure the reported rates are reliable. Determining appropriate approaches to addressing low-volume measurement issues will be imperative for public reporting of REH data given expected low volume of these facilities as evidenced by the numbers of rurally located subsection (d) hospitals with not more than 50 beds and CAHs with sufficient case numbers to have data publicly available on Care Compare. The NQF most recently provided expert panel recommendations for addressing the low volume challenge for performance measurement of rural providers in 2019.[276] The panel recommends, to the extent possible, to ''borrow strength'' (that is, to aggregate measured data over longer timeframes to ensure sufficient data collection for analysis) and leverage expertise and statistical methodology suited to this type of collection. These approaches have been used to model the number of facilities that could achieve sufficient measure volume to produce reliable

[267] In Brief: Rural Behavioral Health: Telehealth Challenges and Opportunities, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (Nov. 2016) *https://store.samhsa.gov/product/In-Brief-Rural-BehavioralHealth-Telehealth-Challenges-and-Opportunities/SMA16-4989.*

[268] *https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/tele-treatment-for-substance-use-disorders/* (Accessed May 31, 2022).

[269] *https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/individual-teletherapy/* (Accessed May 31, 2022).

[270] All-Cause Emergency Department (ED) Utilization for Medicaid Beneficiaries Public Comment Framing Document. *https://cmit.cms.gov/cmit/#/MeasureView?variantId=4867&sectionNumber=1* (Accessed April 8, 2022).

[271] We note that we would not be seeking to propose measures that have been developed for Medicare Advantage plans or for Medicaid beneficiaries as developed for an REHQR Program; we intend only to illustrate that ED utilization is considered an important area for quality measurement.

[272] *https://www.cms.gov/files/document/all-cause-ed-utilization-medicaid-beneficiaries-measure-framing-document.pdf* (Accessed April 7, 2022).

[273] Curcio J, Little A, Bolyard C, et al. (September 17, 2020) Emergency Department ''Bounce-Back'' Rates as a Function of Emergency Medicine Training Year. Cureus 12(9): e10503. *https://doi.org/10.7759/cureus.10503.*

[274] *https://www.cdc.gov/ruralhealth/about.html* (Accessed June 2, 2022).

[275] Centers for Medicare and Medicaid Services (CMS), *Summary of Technical Expert Panel (TEP) Meeting # 1, November 16, 2021: Health Equity Quality Measurement, Hospital Commitment to Health Equity Measure, 2016–2017* (February 2022), available at *https://www.cms.gov/files/document/health-equity-quality-measurement-tep-1-summary-report-hospital-commitment-health-equity.pdf.*

[276] National Quality Forum, *Addressing Low Case-Volume in Healthcare Performance Measurement of Rural Providers: Recommendations from the MAP Rural Health Technical Expert Panel, Final Report* 3 (March 2019) available at *https://www.qualityforum.org/Publications/2019/04/MAP_2019_Recommendations_from_the_Rural_Health_Technical_Expert_Panel_Final_Report.aspx.*

quality measures based on Medicare Fee-For-Service (FFS) claims.

Another panel recommendation is to report exceedance probabilities as an alternate to reporting absolute performance values. An exceedance probability is the probability that a certain value will be exceeded in a predefined future time period; it is often used for predicting the probability of an event. This approach would better reflect the uncertainty of observed quality measure results.[277] For example, an exceedance probability statement might be: ''We can be 84 percent sure that hospital A is performing above the mean on this particular measure.''

We request comment on these recommendations for addressing the low volume issues for performance measurement of rural providers.

C. Quality Reporting Requirements Under the REH Quality Reporting (REHQR) Program

1. Administrative Requirements

Section 1861(kkk)(7)(B)(i) of the Act provides that, with respect to each year beginning with 2023, (or each year beginning on or after the date that is 1 year after one or more measures are first specified under subparagraph (C)), a rural emergency hospital shall submit data to the Secretary in accordance with clause (ii). Clause (ii) states that, with respect to each such year, a rural emergency hospital shall submit to the Secretary data in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph. In this section of the proposed rule, we propose foundational administrative requirements for REHs participating in the REHQR Program.

2. Requirements for Registration on QualityNet and Security Official (SO)

We currently use the CMS QualityNet Secure Portal (referred to as the Hospital Quality Reporting (HQR) secure portal) to host our CMS online data submission tool. To submit quality measure data to CMS using the HQR system, a hospital must establish a secure account through the QualityNet website and designate a Security Official (SO). For more information regarding the HQR system, we refer readers to CY 2022 OPPS/ASC final rule with comment period (85 FR 86179), as well as *https://qualitynet.cms.gov*. An SO must establish user account(s) for the purpose of submitting quality measure data to the HQR system, as well as for authorized users to review and correct data submissions and preview measure information prior to public reporting. The term SO refers to the individual(s) who have responsibilities for security and account management requirements for a facility (85 FR 86182).

Hospitals that currently report quality measure data under CMS quality programs including, but not limited to, the Hospital IQR and Hospital OQR Programs have existing QualityNet accounts. For the CY 2022 payment determination under the Hospital OQR Program, 3,268 hospitals met all reporting requirements including data submission, whereas, only 30 hospitals did not meet all requirements.[278] In addition, of 1,354 CAHs, 1,291 reported data through the Hospital OQR Program. Thus, the vast majority of all subsection (d) hospitals and CAHs have an account for reporting data via the HQR system. The QualityNet and SO registration process should therefore be familiar to many hospitals that convert to being an REH. Thus, we propose that for an REH to participate in the REHQR Program, they must: (1) have an account for the purpose of submitting data to the HQR system. If an REH already has an account for a CMS hospital quality reporting program, the REH can fulfill this requirement by updating its existing account with its new REH CMS Certification Number (CCN). If the REH does not have an account, we are proposing that it must register a new account. Once an REH has an account, it must then (2) have an SO. Since hospitals in the REHQR Program will have new REH CCNs, these hospitals would have to request SO access for the new CCN following the standard instructions posted on the QualityNet website.

From our experience, an SO typically fulfills a variety of responsibilities related to quality reporting such as creating, approving, editing, and terminating user accounts within an organization, and monitoring account usage to maintain proper security and confidentiality protocols. While an SO is initially required to enable a hospital's QualityNet account for data submission and allows the set-up of basic user accounts with capabilities including data submission, it will not be necessary or required to maintain an SO. We highly recommend that hospitals have and maintain a Security Official; though after initial set-up, we reiterate, an SO would not be required.

We invite public comment on this proposal. We intend to propose additional administrative requirements for the REHQR Program in subsequent rulemaking.

XVII. Organ Acquisition Payment Policy

A. Background of Organ Acquisition Payment Policies

The Medicare Program supports organ transplantation by providing an equitable[279] means of payment for the variety of organ acquisition services. Medicare excludes organ acquisition costs from the inpatient hospital prospective diagnosis-related group (DRG) payment for an organ transplant, and separately[280] reimburses transplant hospitals[281] (THs) for their organ acquisition costs under reasonable cost principles[282] under section 1861(v) of the Act, based on the TH's ratio of Medicare usable organs to total usable organs. Medicare authorizes payment to designated independent organ procurement organizations (IOPOs) for kidney acquisition costs, under reasonable cost principles[283] in accordance with section 1861(v) of the Act, based on the IOPO's ratio of Medicare usable kidneys to total usable kidneys (see section 1881(b)(2)(A) of the Act). In accordance with 42 CFR 413.24(f), Medicare requires THs and IOPOs to complete a Medicare cost report[284] on an annual basis.

In the FY 2022 Inpatient Prospective Payment System (IPPS)/Long Term Care Hospital (LTCH) PPS proposed rule (86 FR 25070), which appeared in the **Federal Register** on May 10, 2021, we explained the background and history of Medicare's organ acquisition payment policy and proposed to change, clarify, and codify Medicare organ acquisition payment policies relative to OPOs,[285]

[277] Shwartz M, Peköz EA, Burgess JF Jr, Christiansen CL, Rosen AK, Berlowitz D. A probability metric for identifying high-performing facilities: An application for pay-for performance programs. Med Care. 2014 Dec; 52(2):1030–1036.

[278] *https://qualitynet.cms.gov/outpatient/oqr/apu.*

[279] In this context ''equitable'' means fair and equal to all parties. Medicare recognizes that organ acquisition costs can vary among patients due to different levels of acuity, clinical factors and genetic make-up. Some patients may require different or additional testing and care during the organ acquisition process. Payment under reasonable cost accounts for these differences and ensures that providers are paid appropriately for their share of organ acquisition costs.

[280] 42 CFR 412.2(e)(4) and 412.113(d).

[281] Under 42 CFR 482.70, a transplant hospital is a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

[282] See 42 CFR 412.113(d); HCFA Ruling 87–1 (April 1987); CMS Ruling 1543–R (December 2006).

[283] Id. Section 1138(b)(1)(F) of the Act; 42 CFR 413.1(a)(1)(ii)(A); 413.420(a).

[284] THs complete the hospital cost report on the CMS 2552–10 (OMB No. 0938–0050) and IOPOs complete their cost report on the CMS–216–94 (OMB No. 0938–0102).

[285] We refer to organ procurement organizations generally as ''OPOs'' throughout, unless differentiation of IOPO is required for cost reporting

Continued

THs, and donor community hospitals. We proposed to change the manner in which an organ is counted as a Medicare usable organ for purposes of calculating Medicare's share of organ acquisition costs by counting only organs transplanted into Medicare beneficiaries. We also proposed to codify that Medicare does not share in the costs to procure organs used for research, except where explicitly required by law. In addition, we proposed to require donor community (not transplant) hospitals to bill OPOs their customary charges reduced to costs for services provided to deceased organ donors.

In the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 73416), which appeared in the **Federal Register** on December 27, 2021, we responded to public comments on the proposed rule, and finalized certain proposals to codify longstanding Medicare organ acquisition payment policies, with some modifications, in new subpart L of part 413. We finalized at § 413.418 proposals with respect to donor community hospitals and THs' charges for hospital services provided to deceased donors. We also finalized our proposal to move existing organ acquisition payment regulations, and portions of existing kidney acquisition regulations, within title 42 of CFR part 412, subpart G, and part 413, subpart H, to a new subpart L in part 413, so that all organ acquisition payment policies would be housed together.

We did not finalize our proposal to count as Medicare usable organs only organs transplanted into Medicare beneficiaries. We also did not finalize certain provisions of the proposed policy with respect to counting organs procured for research for purposes of calculating Medicare's share of organ acquisition costs. In the FY 2022 IPPS/LTCH PPS final rule with comment period, we stated that due to the nature of the public comments received, we would address the organ counting policy in subsequent rulemaking, as appropriate.

In this proposed rule, we propose additional revisions, clarifications and codifications pertaining to Medicare's organ acquisition payment policies. In section XVII.B of this proposed rule, we propose changes to how organs procured for research are counted for THs and OPOs for purposes of calculating Medicare's share of organ acquisition costs. In section XVII.C of this proposed rule, we propose that organ acquisition costs include certain hospital costs incurred for services provided to deceased donors. In section XVII.D of this proposed rule, we propose technical corrections to certain regulations. In section XVII.E of this proposed rule, we are clarifying the appropriate allocation of administrative and general costs for THs. Additionally, in section XVII.F of this proposed rule, we are soliciting comments on an alternative methodology for counting organs used in the calculation of Medicare's share of organ acquisition costs; allowing IOPOs to create a SAC for non-renal organs; and Medicare's reconciliation of non-renal organs for IOPOs.

B. Counting Research Organs To Calculate Medicare's Share of Organ Acquisition Costs

In the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 73470), we clarified that for Medicare payment purposes, Medicare does not include in Medicare's share of organ acquisition costs the costs to procure an organ for research, except where explicitly required by law. Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provided Medicare coverage of pancreata for islet cell transplant for beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial. An exception for Medicare cost allocation purposes for pancreata for islet cell transplant for these trials is under § 413.406(a). Under §§ 413.5(c)(2) and 413.90(a), costs incurred for research purposes, over and above usual patient care, are not includable as Medicare allowable costs.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25668), we clarified that for organ acquisition cost allocation purposes, a ''research organ'' is an organ procured and used for research regardless of whether it is transplanted as part of clinical care (with the exception of certain pancreata). We proposed to codify that organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except certain pancreata procured for islet cell transplants). We also proposed that OPOs and THs do not count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs as Medicare usable organs but count as total usable organs. Finally, we proposed that OPOs and THs do not count organs designated for transplant prior to the time the donor entered the hospital's operating room for surgical removal of the organs but subsequently determined to be unusable and donated to research, as Medicare usable organs or total usable organs.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we finalized our proposal to require that organs used for research be excluded from Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)), and kidneys used for research be excluded from Medicare usable kidneys in Medicare's share of kidney acquisition costs under § 413.412(c). However, due to the number and nature of the comments received, we did not finalize our proposal that would have required OPOs and THs to include organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs in the count of total usable organs or our proposal to exclude organs designated for transplant but subsequently determined to be unusable and donated to research from Medicare usable organs or total usable organs. We indicated that we may address these issues in future rulemaking.

Commenters on these proposals overall expressed concern that our proposals would negatively impact the affordability and availability of research organs and hinder the advancement of clinical research (86 FR 73494). Some commenters suggested that including research organs in the count of total usable organs reflected a change in policy for IOPOs that would require assignment of a full SAC (including administrative, general, and overhead costs) to each research organ they procured and would also result in significantly higher acquisition costs that would be borne by the research community. One commenter suggested that our proposal to exclude organs donated for research from the count of Medicare and total usable organs would result in procurement costs being passed on to researchers, which could discourage the use of human organs in research studies. A few commenters reported that IOPOs charge researchers an agreed upon fee for furnishing an organ for use in research. They asserted that if our proposal to include organs in the count of total usable organs were finalized, IOPOs would need to charge significantly higher amounts for furnishing research organs to the research community. A few commenters noted that procuring an organ for use in research may involve less extensive testing and evaluation than is necessary when procuring an organ for

purposes for OPOs that file a cost report on the CMS–216–94 (OMB No. 0938–0102).

transplantation. We believe that most THs and OPOs currently charge the research community agreed upon prices to procure research organs instead of charging a SAC. We have heard from some interested parties in the transplant community that THs and OPOs use agreed upon pricing because the SAC may include procurement services that are unnecessary to procure research organs.

In the time since we issued the FY 2022 IPPS/LTCH PPS final rule with comment period, we have continued to review the potential impacts of our research organ proposal on stakeholders. We agree with the comments on the FY 2022 IPPS/LTCH PPS proposed rule that suggested that including research organs in the count of total usable organs would require the assignment of a full SAC on the Medicare cost report for each research organ procured. We understand that this practice may increase the amount the research community pays for obtaining organs for research. We also recognize that procurement costs may differ for research organs and transplanted organs because organs procured for research may be subject to less extensive testing and evaluation than organs that are to be transplanted. We believe that when THs and OPOs furnish organs for research, they should charge amounts that more accurately reflect the testing and evaluation associated with procuring research organs. This amount should represent the actual costs incurred by the TH or OPO for furnishing organs used for research instead of a token fee that does not cover the procurement cost of the organs.

In response to commenters' concerns with the research organ counting proposals in the FY 2022 IPPS/LTCH PPS proposed rule, in this proposed rule we propose to require that THs and OPOs exclude organs used for research from the numerator (Medicare usable organs) and the denominator (total usable organs) of the calculation used to determine Medicare's share of organ acquisition costs on the Medicare cost report. For the purpose of determining Medicare's share of organ acquisition costs, we intend a ''research organ'' to be an organ used for research (with the exception of certain pancreata), regardless of whether the organ was intended for research, or intended for transplant under § 413.412(a) and instead used for research. Including organs used for research in the count of Medicare usable organs and total usable organs results in assignment of a full SAC to each research organ. Our proposal would not require assignment of a full SAC on the Medicare cost report for each research organ procured; and therefore, would not result in a significant increase in amounts charged for research organs. We expect that when an organ, identified as a research organ, is transplanted into a patient, the organ is counted as a total usable organ and a full SAC is assigned.

Under our proposal, THs and OPOs would also be required to deduct the cost incurred in procuring an organ for research from their total organ acquisition costs. This process would ensure that research organ procurement costs are not allocated across all transplantable organs and consequently, that Medicare is not paying for non-allowable research activities. Additionally, this practice would ensure that Medicare does not pay for non-allowable research costs in instances where the TH or OPO charges a fee that does not cover the cost it incurred to procure the organ for research.

Although TH/HOPOs are currently including research organs in the total usable organ [286] count and assigning a full SAC to each research organ, we believe this proposal, if finalized, would not affect the TH/HOPOs ability to charge research entities a fair and accurate amount for procuring organs used for research. THs and OPOs are responsible for negotiating the amount charged for an organ used for research with the research entity receiving the research organ; however, regardless of amounts charged, the costs must be offset against total organ acquisition costs. In accordance with 42 U.S.C. 273(b)(1)(B) and § 486.303(c), OPOs are required to have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization.

The availability of organs for research is important for continued innovation in transplant medicine and for the discovery of new treatments for diseases. In order to ensure the research community has access to organs for research and to lower the procurement costs associated with such organs, we propose to revise the policy set forth in § 413.412(c) for OPOs and THs for counting organs used for research. Specifically, we propose to revise § 413.412(c) as follows: first, by redesignating paragraph (c) (after the subparagraph heading) as paragraph (c)(1); second, by revising redesignated paragraph (c)(1) to specify that for Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs or as total usable organs in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a) and, third, by striking the language that specifies that kidneys used for research are not counted as Medicare usable kidneys or as total usable kidneys in Medicare's share of kidney acquisition costs; (we believe this language is duplicative because the reference to ''organs'' includes kidneys). We also propose to amend § 413.412(c) by adding paragraph (c)(2) which would require that OPOs and THs must reduce their costs to procure organs for research from total organ acquisition costs on the Medicare cost report.

Regarding the counting of unusable organs as described in § 413.412(d), we propose to remove the specification that the determination that an organ is unusable is made by the *excising* surgeon; our proposed amendment would allow this determination to be made by any surgeon. As revised, paragraph (d)—which we propose to redesignate as paragraph (d)(1)—would provide that an organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable. In addition, we propose to clarify in § 413.412(d) that Medicare shares in the costs to procure unusable organs through the application of the Medicare ratio and to clarify how OPOs and THs must report these organs on their Medicare cost reports to ensure that Medicare shares in the costs to procure these organs. Specifically, we propose to add new paragraph (d)(2), which would specify that OPOs and THs include the costs to procure unusable organs, as described in § 413.412(d)(1), in total organ acquisition costs reported on their Medicare cost reports.

C. Costs of Certain Services Furnished to Potential Deceased Donors

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we codified at § 413.418(a) our longstanding policy that only costs incurred after the declaration of the donor's death and consent to donate are permitted to be included as organ acquisition costs (86 FR 73500 through 73503). However, after finalizing that rule, we received feedback from some stakeholders that indicated that OPOs may incur certain costs for donor management prior to declaration of death, but when death is imminent, in accordance with OPTN

[286] CMS 2552–10 (OMB No. 0938–0050).

donation policies.[287] This is typical in cases of donation after cardiac death (DCD). We researched this issue further and found that these costs are for certain services that can only be performed prior to declaration of death, when death is imminent, to evaluate the organs for transplant viability and to prepare the donor for donation. Failure to provide these services to the potential donor may compromise the viability of organs, limit organ donation, and would not honor the donor or donor family's wishes to donate organs. To avoid these unintended consequences, we propose to modify § 413.418(a) to allow a donor community hospital or TH to incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. Organ acquisition costs include hospital services authorized by the OPO when there is consent to donate, and a declaration of death has been made or death is imminent and these services must be provided prior to declaration of death. These costs must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team.

Under this proposal, hospitals would bill the OPO for these services in accordance with § 413.418(b), and the OPO would record those billed amounts as organ acquisition costs on its Medicare cost report. Because these services are intended to determine or maintain the viability of organs for transplant, the patient's health insurance would not be billed for the organ acquisition costs, and the patient or patient's family would not be responsible for those amounts. Stakeholders were concerned that without this clarification, if services authorized by the OPO and provided by the hospital could not be included as organ acquisition costs, hospitals may bill the donor's family or a third-party payor. Doing so could create a barrier to organ donation based on economic means, by forcing costs associated with organ acquisition to be borne by the donor's family or a third-party payor. Making the donor's family responsible for these costs could preclude those of lesser economic means from fulfilling their wishes to donate organs and would be inequitable. It could also be a deterrent to deceased donor organ donation and as a result reduce the supply of organs available for transplant. We are committed to supporting organ donation in an equitable fashion and view this issue as a potential barrier to organ donation. We believe our proposal supports organ donation and organ procurement costs and addresses a potential inequity in the transplant ecosystem.

D. Technical Corrections and Clarifications to 42 CFR 405.1801, 412.100, 413.198, 413.402, 413.404, 413.420 and Nomenclature Changes to 42 CFR 412.100 and 42 CFR Part 413, Subpart L

Technical Corrections and Clarifications. In the FY 2022 IPPS/LTCH PPS final rule with comment period, § 413.200 was reserved and redesignated as § 413.420 with revisions. In this proposed rule, we propose to make a technical correction to § 405.1801(b)(2)(ii), by removing the reference to § 413.200(g) and replacing it with a reference to § 413.420(g). We also propose to make a technical correction to § 413.198(b)(4)(ii), by removing the reference to ''Section 413.200, Reimbursement of OPAs and histocompatibility laboratories'' and replacing it with a reference to ''Section 413.420,'' and that section's title, ''Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.''

We also propose to clarify §§ 412.100(b) and 413.402(a) by removing ''as appropriate'' and instead specifying that organ acquisition costs are allowable costs incurred in the acquisition of organs from a living donor or a deceased donor by a hospital, or from a deceased donor by an OPO.

We propose to revise § 413.404(c)(2)(i)(C) so that it is written in the active voice and not the passive voice. In addition, we propose to revise this provision to clarify that the kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in § 413.420(d)(1).

We propose to amend § 413.420(a)(1) by striking ''after September 30, 1978,'' as we believe it is no longer necessary that the regulations specify that the reasonable cost reimbursement principles in part 413 only apply to covered services furnished after that date; and to replace the acronym ''OPOs'' with ''IOPOs''. We propose to amend § 413.420(a)(2) to correct a typographical error by changing ''HOPOs'' to ''IOPOs''.

We propose to amend § 413.420(c)(1)(v) to correct the statutory reference to section 1861 of the Act so that it instead refers to section 1881 of the Act; the original regulation text was in § 413.178, and was redesignated as § 413.200 in 1997[288] before being redesignated as § 413.420 in the FY 2022 IPPS/LTCH PPS final rule with comment period.[289] The original regulation at § 413.178 referred to section 1881 of the Act, but a typographical error changed ''1881'' to ''1861'' when other changes to the regulation were proposed in 1987 (52 FR 28674) and finalized in 1988 (53 FR 6548).

Nomenclature Changes. In this proposed rule, we propose to amend §§ 412.100(b); 413.402(a) and (b)(3), (4), (7) and (8)(ii); 413.404(a)(2), (b)(3), and (c)(1)(i) and (ii); and 413.418 (the section title and paragraph (b)), by replacing the term ''cadaveric'' with ''deceased'', to be consistent with terminology used within the transplant community when referring to deceased donors, and to promote sensitivity regarding the process and decision of donating organs from deceased donors. In § 413.404(b)(3)(ii), we propose to replace ''cadaveric SAC'' with ''deceased donor SAC'' and ''cadaveric organ(s)'' with ''deceased donor organ(s)''; and in § 413.404(c)(2), we propose to replace ''cadaveric kidneys'' with ''deceased donor kidneys''.

We propose to amend § 413.404(c)(2)(i)(A), (B), and (D) and 413.414(c)(1) by replacing references to ''Medicare contractor'' with ''contractor'', to conform to terminology changes made in the FY 2015 IPPS final rule (79 FR 49854 at 50199) and in accordance with the definition at 42 CFR 405.201(b).[290]

In this proposed rule, we also propose to remove the term ''discarded'' from § 413.412(d) and replace it with ''unusable'', to promote sensitivity in scenarios where donated organs are unused because they are not suitable for transplantation.

Finally, in this proposed rule, we propose to amend § 413.400 by adding ''TH'' in parentheses after the defined term ''transplant hospital''. Throughout subpart L, we propose to replace the term ''transplant hospital'' with ''TH''.

E. Clarification of Allocation of Administrative and General Costs

When a TH procures organs for transplantation, it is required to allocate administrative and general (A&G) costs to the appropriate organ acquisition cost centers on its Medicare hospital cost

[287] OPTN Policy Manual, Policy 2, available at *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf,* accessed February 4, 2022.

[288] 62 FR 43668, Aug. 15, 1997.

[289] 86 FR 73515, Dec. 27, 2021.

[290] 42 CFR 405.201(b) defines contractors as Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

report (MCR).[291] This practice is in accordance with Medicare's reasonable cost principles under section 1861(v) of the Act and the regulations at §§ 413.20 and 413.24. When a TH receives organs from an OPO or other TH, it makes payment to the OPO or TH that furnished the organ for the cost incurred to procure the organ. We are aware that some THs that receive organs place the ''purchase cost'' for the organs they receive in the accumulated cost statistic by which A&G is allocated. Under § 413.24(d)(6), including a statistical cost which does not relate to the allocation of A&G expenses causes an improper distribution of overhead and could result in improper Medicare payment. In this scenario, when the receiving TH includes the purchase cost of the organ it received in the statistical cost by which A&G is allocated, overhead is improperly distributed to the receiving TH organ acquisition cost center.

To ensure the appropriate allocation of A&G costs on a TH's MCR, we propose to clarify that when a TH receives organs from an OPO or other TH, the receiving TH must exclude from its accumulated cost statistic the cost associated with these organs because these costs already include A&G costs. In accordance with § 413.24(d)(6), purchased services for a department that are directly assigned to the department that include A&G costs result in an excessive allocation of overhead. This duplication of A&G costs results in improper Medicare payment to the provider. In accordance with MCR instructions,[292] if some of the costs in the department that received this direct assignment of purchased services should receive A&G costs, the TH must remove the directly assigned costs (purchased services) from its allocation statistic to assure a proper allocation of overhead. This process facilitates appropriate Medicare payment and ensures that the receiving TH's organ acquisition cost center does not receive an improper distribution of overhead costs that it did not incur. These longstanding Medicare cost finding principles are in accordance with § 413.24(d)(6), and specifically expressed in the MCR instructions for THs.[293]

F. Organ Payment Policy—Request for Information on Counting Organs for Medicare's Share of Organ Acquisition Costs, IOPO Kidney SACs, and Reconciliation of All Organs for IOPOs

In this proposed rule, we are requesting information on an alternative methodology for counting organs for purposes of calculating Medicare's share of organ acquisition costs; IOPOs' kidney SACs; and Medicare's reconciliation of all organs for IOPOs. While we will not be responding to specific comments submitted in response to this RFI in the CY 2023 OPPS final rule, we intend to use this input to inform future policy development.

1. Counting Organs for Medicare's Share of Organ Acquisition Costs

Medicare calculates its share of organ acquisition costs for THs/HOPOs by multiplying the allowable organ acquisition costs by the ratio of Medicare usable organs (the numerator) to total usable organs (the denominator) reported on the Medicare hospital cost report.[294] Currently, THs/HOPOs must include the following as Medicare usable organs in the numerator of the Medicare share fraction:[295] (1) organs transplanted into Medicare beneficiaries; (2) organs transplanted into Medicare beneficiaries that were partially paid by a primary insurance payor in addition to Medicare; (3) organs sent to other THs or OPOs; (4) kidneys transplanted into Medicare Advantage beneficiaries for dates of service on or after January 1, 2021;[296] (5) kidneys sent to United States military renal transplant centers (MRTCs) with a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988, and approved by the contractor; and (6) pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial pursuant to section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173); 42 U.S.C 1395l (MMA).[297] However, ''(3) organs sent to other THs or OPOs'' and ''(5) kidneys sent to United States MRTCs with a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988, and approved by the contractor,'' may include organs that are not actually transplanted into Medicare beneficiaries. Including organs that are not transplanted into Medicare beneficiaries in Medicare usable organs inflates Medicare's share of organ acquisition costs.

Currently, THs/HOPOs must include the following as total usable organs in the denominator of the Medicare share fraction: (1) Medicare usable organs; (2) organs excised with the intention to be used for research; (3) organs excised and either transplanted or furnished to other THs or OPOs; (4) organs obtained from another TH or OPO and either transplanted or furnished to other THs or OPOs; (5) organs furnished to veterans' hospitals or organs sent outside the United States, under § 413.203; (6) organs transplanted into non-Medicare beneficiaries, under § 413.203; (7) organs for which the transplant was totally or partially paid by primary insurance other than Medicare; (8) kidneys furnished to United States MRTCs with or without a contractor approved reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988; and (9) pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with the MMA.[298]

For IOPOs, Medicare calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys (the numerator) to total usable kidneys (the denominator) reported on the Medicare IOPO cost report.[299] Currently, IOPOs must include the following as Medicare usable kidneys: (1) kidneys sent to THs; (2) kidneys sent to certified OPOs; and (3) kidneys sent to United States MRTCs with a reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988, and approved by the contractor. However, not all kidneys that are counted as Medicare usable kidneys are

[291] CMS 2552–10 (OMB No. 0938–0050)

[292] PRM 15–2, chapter 40, section 4020.

[293] Id.

[294] CMS Pub. 15–2, chapter 40, section 4028.

[295] Pursuant to PRM § 3115.A. and CMS Pub. 15–2, chapter 40, section 4028.3.

[296] Section 17006 of the 21st Century Cures Act, (Pub. L. 114–255). Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs are covered under the original Medicare FFS program. The MA kidney transplants are included in the numerator and denominator on the MCR to determine Medicare's share of kidney acquisition costs (85 FR 33796, 33824, June 2, 2020).

[297] Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173); 42 U.S.C. 1395l.

[298] Id.

[299] CMS Pub. 15–2, chapter 33, section 3312.

transplanted into Medicare beneficiaries.

IOPOs must currently include the following as total usable kidneys: (1) Medicare usable kidneys; (2) kidneys procured and furnished to other THs or OPOs; (3) kidneys furnished to veterans' hospitals or organs sent outside the United States in accordance with § 413.203; (4) kidneys for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; and (5) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25656), we provided a historical overview of Medicare's organ acquisition payment policy to explain why Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries. When Medicare added the ESRD benefit to Medicare coverage in 1972, Medicare presumed that most kidney transplant recipients would be Medicare beneficiaries receiving the ESRD benefit, and thus Medicare would pay a larger share of kidney acquisition costs.[300] As Medicare added benefits for transplantation of non-renal organs and included the costs to procure non-renal organs, Medicare cost reporting instructions incorporated the presumption that the ultimate transplant recipient was unknown, but likely a Medicare beneficiary. Currently, when a TH sends an organ to another TH or to an OPO, or when an OPO sends an organ to another OPO or to a TH, Medicare assumes that some of the unknown transplant recipients are Medicare beneficiaries, and permits those organs to be counted as Medicare usable organs in the numerator of the fraction for Medicare usable organs to total usable organs, to be assured that Medicare is paying its share of organ acquisition costs. Thus, some organs that are not ultimately transplanted into Medicare beneficiaries are currently being included in ''Medicare usable organs'' or ''Medicare usable kidneys'', resulting in Medicare paying more than its share of organ acquisition costs (86 FR 25665).

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25664), we stated that Medicare does not intend to share in the cost of procuring organs that are not transplanted into Medicare beneficiaries (except those organs designated for transplant but subsequently determined to be unusable). In the 1988 proposed rule titled ''Medicare Program; Payment for Kidneys Sent to Foreign Countries or Transplanted in Non-Medicare Beneficiaries'' (53 FR 6672, 6673), which appeared in the **Federal Register** on March 2, 1988, CMS stated that allowing all kidneys to be counted as Medicare kidneys was not aligned with anti-cross subsidization principles set forth in section 1861(v)(1)(A) of the Act. CMS (which was at that time known as the Health Care Financing Administration, or HCFA) observed that the Medicare Program had been paying the cost of procuring kidneys transplanted into non-Medicare beneficiaries and stated it was necessary to amend the regulations in order to effectuate the statutory principles embodied in section 1861(v)(1)(A), including that the cost of services be borne by the appropriate payor. We stated that the cost associated with the kidneys not used by Medicare beneficiaries must be borne by the responsible individual or third-party payor and that Medicare is precluded from paying any costs associated with kidneys not used by Medicare beneficiaries. We proposed to establish in the regulations at Part 413 a requirement for OPOs to reduce their acquisition costs for kidneys furnished to foreign transplant centers and kidneys transplanted in non-Medicare patients, which would be achieved by including these kidneys in total usable kidneys and excluding them from Medicare usable kidneys. This proposal was finalized in the final rule titled ''Medicare Program; Payment for Kidneys Sent to Foreign Countries or Transplanted in Patients Other Than Medicare Beneficiaries'' (54 FR 5619) and currently appears at § 413.202.[301] Similarly, under § 413.203, THs are required to reduce their acquisition costs for organs they furnish to foreign transplant centers and organs transplanted in non-Medicare patients. This is achieved by including these organs in total usable organs and excluding them from Medicare usable organs.

In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to require that THs count the number of organs, and IOPOs count the number of kidneys, actually transplanted into Medicare beneficiaries on their Medicare cost reports to more accurately calculate Medicare's share of organ acquisition costs. Our proposal used the current methodology to calculate Medicare's share where for THs, organs furnished to other THs or OPOs are included in the numerator and denominator of the Medicare fraction, and for IOPOs, kidneys furnished to other OPOs or THs are included in the numerator and denominator of the Medicare fraction. Under our proposal, THs and IOPOs would have been required to track organs they furnish to other facilities and to determine and report on their Medicare cost reports, the number of those organs that were transplanted into Medicare beneficiaries.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we stated that we were not finalizing the organ counting proposals included in the FY 2022 IPPS/LTCH PPS proposed rule, due to the number and nature of the comments received, and we indicated we may revisit this issue in future rulemaking. Many commenters expressed acknowledgment and understanding of CMS' objective to pay for organ acquisition costs for only organs transplanted into Medicare beneficiaries. However, commenters expressed concerns over potential operational challenges and increases in burden for THs and OPOs if CMS were to finalize the proposal and require tracking of organs furnished to other THs and OPOs, from donors to recipients. Commenters also expressed concern over the revenue reductions that OPOs and THs, particularly THs that are children's hospitals, were expected to experience under the proposal to count only organs transplanted into Medicare beneficiaries as Medicare usable organs. Many commenters indicated that because of their traditionally very low Medicare utilization, THs that are children's hospitals would experience a greater financial burden under the proposed organ counting methodology than would be experienced by THs that are not children's hospitals. Commenters indicated that THs that are children's hospitals would have difficulty in making up for the loss of Medicare revenue from other payor sources. Commenters indicated that stakeholders would need more time to renegotiate contracts with other payors, including Medicaid payments from states. Commenters expressed concern over the potential impact on the transplantation

[300] Intermediary Letter 73–25 (July 1973) and 54 FR 5619, February 6, 1989.

[301] The requirement in § 413.202 (titled ''Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries'' (titled ''Organ procurement agencies' (OPAs') or transplant centers' costs for kidneys sent to foreign countries or transplanted in non-Medicare beneficiaries''), was originally codified under § 413.179 (54 FR 5619, February 6, 1989). Section 413.179 was subsequently redesignated as § 413.202 (62 FR 43665, August 15, 1997)).

ecosystem and suggested the proposed policy would result in a decreased organ supply, although they did not explain how the proposed policy might cause this to occur. Commenters asked CMS to either withdraw the proposal or delay its implementation. Commenters also requested that CMS conduct additional analyses.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we indicated that we would conduct additional analyses of impacts upon THs, children's hospitals, and OPOs before considering a possible re-proposal in future rulemaking of a policy that would only count organs transplanted into Medicare beneficiaries for purposes of calculating Medicare's share of organ acquisition costs. We examined the states where the children's transplant hospitals are located and how often their State legislatures meet. We found that all children's hospitals that are certified as THs are in states where legislatures meet annually, except for four children's hospitals located in Texas, where the legislature meets biennially.

Due to the comments received on the FY 2022 IPPS/LTCH PPS proposed rule, in this RFI we are seeking information as we consider an alternative methodology for counting organs that will not require THs and OPOs to track exported organs but would require TH/HOPOs and OPOs to report only organs transplanted into Medicare beneficiaries for purposes of calculating Medicare's share of organ acquisition costs. Under such methodology, TH/HOPOs would include as Medicare usable organs only organs transplanted within their TH into Medicare beneficiaries. In this regard, we would exclude organs that a TH furnishes to other THs or OPOs from its Medicare share fraction, in both the numerator (Medicare usable organs) and denominator (total usable organs), and require revenue offsets against total organ acquisition costs for these organs. Such a methodology would result in an apportionment of costs and redistribution of reasonable organ acquisition costs to only organs transplanted into Medicare beneficiaries within the recipient TH, but it would not require TH/HOPOs to track organs they furnish to other THs and OPOs, removing a burden that was concerning to many commenters on the FY 2022 IPPS/LTCH PPS proposed rule.

For OPOs, we are considering an alternative methodology for counting organs where OPOs would count all organs, not just kidneys, and calculate Medicare's share of organ acquisition costs using a ratio of Medicare usable organs to total usable organs. OPOs would include in Medicare usable organs only organs transplanted into Medicare beneficiaries, using recipient payor data provided to OPOs by the OPTN. Under such a methodology, OPOs would also be required to offset total organ acquisition costs with revenue received for Medicare usable organs. Under the methodology, IOPOs would not be required to track organs they furnish to other OPOs or THs to determine whether the organ recipient is a Medicare beneficiary, removing a burden that was concerning to many commenters on the FY 2022 IPPS/LTCH PPS proposed rule. Such a methodology would result in an apportionment of costs and redistribution of reasonable organ acquisition costs to only organs transplanted into Medicare beneficiaries.

We would like to better understand and obtain more detailed information on the extent to which THs, OPOs, and other interested parties would be impacted under these alternative organ counting methodologies used to calculate Medicare's share of organ acquisition costs. Specifically, CMS seeks public comment on the following:

1. What proportion of organs used for transplant are acquired by your hospital, received from other THs directly, or received from OPOs? Does this vary by type of organ, age category, or insurance status of the potential recipient and if so, how?

2. Of all the transplants performed in your hospital in the past 5 years, what percentage were for:

(a) Medicare beneficiaries; (b) Medicaid patients; (c) private pay patients; (d) patients who receive financial assistance for services provided at a free or reduced rate?

3. Describe how THs and OPOs currently support organ acquisition costs financially. What revenue and income streams (for example, grants, fundraising, etc.) support these activities?

4. Are you able to quantify the revenue your facility has received over the past 5 years resulting from Medicare's organ counting policy because acquisition costs were assigned to Medicare usable organs for THs, or Medicare usable kidneys for IOPOs, that were transplanted into non-Medicare beneficiaries? If so, what are the amounts?

5. Describe the impact of the revenue reduction resulting from an alternate organ counting methodology, both in absolute terms and relative to your IOPO, or transplant program and hospital as a whole.

6. Should children's hospitals be treated differently under an alternate organ counting methodology, and if so, why and how?

7. In your State, does Medicaid cover organ transplants and acquisition costs? If so, explain the Medicaid payment methodology. Would an alternative organ counting methodology to calculate Medicare's share of organ acquisition costs impact your payments received from Medicaid for transplants and/or organ acquisition costs? Additionally, would a potential change in organ counting affect access to care, and if so, how?

8. Do other payors pay equitably to share in the costs to acquire organs for transplant for their patients? If so, under an alternate organ counting methodology for Medicare would all payors, including Medicaid, continue to equitably share in the cost to acquire organs for transplant? By ''equitably'', we mean other payors pay their share of organ acquisition costs for organs transplanted into their respective patients.

9. If an alternate organ counting methodology were implemented, are there any timing issues for implementation that we should consider regarding other payors, including State Medicaid Agencies, to address their organ acquisition and/or transplant payment methodologies?

10. Describe what services your TH or IOPO may need to reduce or change to accommodate a reduction in revenue from Medicare stemming from an alternate organ counting methodology to count only organs transplanted into Medicare beneficiaries to calculate Medicare's share of organ acquisition costs.

11. Will your facility perform less transplants if revenue is eliminated from Medicare under an alternate organ counting methodology? If so, why and how? Will your facility perform less organ acquisitions if revenue is eliminated from Medicare under an alternate organ counting methodology? If so, why and how?

12. Is the cost to acquire an organ for transplantation into a Medicare beneficiary different than the cost to acquire an organ for transplantation into a non-Medicare beneficiary? If so, what factors contribute to the difference in organ acquisition costs?

13. Describe how clinical decision-making affects organ allocation and transplantation. Are there other factors that affect organ allocation and transplantation that we should be aware of?

2. IOPO Kidney Standard Acquisition Charges

Currently, the contractor [302] establishes each IOPO's kidney SAC, and adjusts it if necessary, in accordance with § 413.404(c)(2). IOPOs must bill their kidney SAC for the costs of Medicare and non-Medicare kidneys procured for transplant, and are paid their SAC amount by the entity receiving the kidney (§ 413.404(c)(3)). At the end of the cost reporting period, the contractor reconciles the IOPO's Medicare kidney acquisition costs with the revenue the IOPO received for those kidneys, and settles with the IOPO to ensure it is paid the reasonable costs of Medicare kidney acquisition (§ 413.420(e)(2)).[303]

Currently, IOPOs count almost all of the kidneys they procure as Medicare usable kidneys. (Kidneys sent outside of the United States are not counted as Medicare usable kidneys.) Consequently, Medicare's current share of kidney acquisition costs is nearly 100 percent, and the reconciliation process currently makes the IOPO whole for nearly all its kidney acquisition costs, on a reasonable cost basis. However, not all kidneys that are counted as Medicare usable kidneys are transplanted into Medicare beneficiaries; some of those kidneys are transplanted into patients with Medicaid, private insurance, etc. As discussed in the Request for Information (RFI) in section XVII.F.1 of this proposed rule, we are considering an alternative organ counting methodology that would require IOPOs to count as Medicare usable organs only those organs that are actually transplanted into Medicare beneficiaries, including renal and non-renal organs. Such a methodology would result in IOPOs' organ acquisition costs being reconciled and settled for all organ acquisition costs for organs actually transplanted into Medicare beneficiaries.

Additionally, for kidneys, such an alternative organ counting methodology would limit the kidney revenue IOPOs receive from THs and other OPOs to the kidney SAC amount. Longstanding policy currently requires the contractor to establish the kidney SAC amount (§ 413.404(c)(2)). To ensure that an IOPO's kidney SAC appropriately covers its costs, we are considering a methodology under which IOPOs, rather than the Medicare contractor, would establish their kidney SACs, similar to how they establish their SACs for non-renal organs. This alternative methodology would place the fiscal responsibility on the IOPOs for kidneys, similar to non-renal organs, by placing the IOPO in control of its kidney acquisition revenue stream through control of its kidney SAC.

Specifically, we are considering an alternative methodology where an IOPO would estimate the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor kidneys during its cost reporting period and divide that estimated amount by the projected number of deceased donor kidneys the IOPO expects to procure within its cost reporting period. We are also considering a potential policy approach that would permit an IOPO to adjust its kidney SAC during the year, if necessary, to account for cost changes. We believe these alternative policy approaches are in alignment with section 371(b)(1)(B) of the Public Health Service Act and the conditions of participation at § 486.303(c), which require OPOs to have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to THs.

We are requesting information on these alternative policy approaches that we are considering related to the IOPO kidney SAC. Specifically, we are seeking information pertaining to the following questions:

1. Do IOPOs have any concerns with establishing (and where necessary, adjusting) their own kidney SAC, in accordance with the potential policy approach under consideration? Do IOPOs have any concerns with the potential methodology under consideration for calculating the kidney SAC amount?

2. We have heard from stakeholders that some IOPOs have lengthy internal processes to adjust their SACs. Do IOPOs have the ability to respond quickly to cost changes that might necessitate a SAC adjustment? How frequently do IOPOs currently need to adjust their SACs due to cost changes that are higher or lower than usual?

3. Are there specific high cost items or services associated with organ procurement that potentially could increase a SAC? If yes, please explain. What rules or parameters should CMS consider to account for these items or services when developing a potential methodology for how IOPOs calculate their SACs?

4. Do IOPOs believe that being in control of their kidney SAC, as they are of their non-renal organ SACs, would improve their fiscal stability?

5. Do stakeholders have concerns about IOPOs establishing their kidney SACs?

3. Reconciliation for All Organs for IOPOs

Currently, the contractor is required to review IOPOs' kidney acquisition costs and reconcile and settle those costs to ensure that Medicare pays its share on a reasonable cost basis. However, there is no similar requirement for the contractor to review, reconcile and settle IOPOs' non-renal organ acquisition costs. Over the years, through various rulings and national coverage determinations (NCDs), Medicare has added coverage for transplantation of non-renal organs such as heart, liver, or lungs. Non-renal organs were covered for transplantation through a CMS Ruling (for heart transplants) and through NCDs (for other non-renal organs),[304] and payment policies were subsequently implemented through notice-and-comment rulemaking.[305] We modeled our reimbursement for non-renal organ acquisition costs on our earlier kidney acquisition policies. In addition, the OIG [306] and Congress [307] have expressed concerns regarding some OPOs' financial practices. As such, we believe there is a need to provide more contractor review of non-renal organ acquisition costs to protect the Medicare Trust Fund and the transplant ecosystem. Therefore, we are considering a requirement that the contractor review, reconcile and settle Medicare's share of costs to acquire non-renal organs for IOPOs under reasonable

[302] ''Contractor'' refers to the Medicare Administrative Contractor (MAC) and conforms to terminology changes made in the FY 2015 IPPS final rule (79 FR 50199) and with the definition given at 42 CFR 405.201(b).

[303] Section 1861(v) of the Act requires that certain Medicare services, including organ acquisition costs, must be paid based on reasonable cost.

[304] See CMS Ruling 87–1, April 1987; National Coverage Determinations Manual, IOM 100–03, chapter 1, Part 4, section 260 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf*).

[305] 52 FR 33034, September 1, 1987 (heart); 55 FR 8545, March 8, 1990 and 56 FR 15013, April 12, 1991 (liver); 60 FR 6537, February 2, 1995 (lung); 64 FR 41497, July 30, 1999 (pancreas); 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001).

[306] *https://oig.hhs.gov/oas/reports/region9/90800033.pdf; https://oig.hhs.gov/oas/reports/region9/90900087.pdf; https://oig.hhs.gov/oas/reports/region9/90500034A.pdf; https://oig.hhs.gov/oas/reports/region9/91102039.pdf.*

[307] *https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-* and *https://www.young.senate.gov/newsroom/press-releases/young-joins-finance-committee-members-to-probe-us-organ-transplant-system; https://www.congress.gov/117/chrg/CHRG-117hhrg44569/CHRG-117hhrg44569.pdf.*

cost principles, similar to the current practice for kidneys.

To reconcile Medicare's share of non-renal organ acquisition costs, the contractor would review the Medicare cost report to determine if the costs are reasonable. This would entail the contractor's review of all IOPO organ acquisition costs, and would ensure that IOPOs' costs that are reported as organ acquisition costs are appropriate, in accordance with § 413.402, and are reasonable and necessary, in accordance with section 1861(v) of the Act and §§ 413.5 and 413.9.

If an IOPO establishes a non-renal SAC that is higher than its reasonable costs, that higher charge becomes an inflated non-renal organ acquisition cost to the TH or other OPO receiving the organ. Medicare shares in these inflated costs as a portion are ultimately paid by Medicare when Medicare reconciles THs' organ acquisition costs. Without reconciliation and settlement of IOPOs' non-renal organ acquisition costs, Medicare cannot recover those inflated costs, resulting in Medicare paying more than reasonable costs for Medicare's share of organ acquisitions. Conversely, if an IOPO establishes a non-renal SAC that is less than its reasonable costs, the charge becomes an organ acquisition cost to the TH receiving the organ. The lower costs are ultimately paid to the TH by Medicare when reconciled through the TH's Medicare cost report. Without reconciliation and settlement of IOPOs' non-renal organ acquisition costs, Medicare is unable to make IOPOs whole for Medicare's share of the reasonable costs. If IOPOs are consistently underpaid for their non-renal Medicare organ acquisitions costs because IOPOs establish SACs that are too low, their fiscal stability could be compromised.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25675), we proposed regulatory changes to § 413.200, and a commenter expressed concern that CMS did not make a proposal to reconcile and settle an IOPO's non-renal organ acquisition costs. The commenter noted that not reconciling and settling IOPO non-renal organ acquisition costs could result in fewer non-renal organs being made available for transplant when an IOPO's total non-renal organ acquisition costs exceed the total revenue the IOPO receives for organs it provides to other OPOs or THs. In the FY 2022 IPPS/LTCH PPS final rule with comment period, we responded that we would consider this issue in future rulemaking (86 FR 73479). While the inconsistency in reconciliation and settlement of renal and non-renal organ acquisition costs may compromise fiscal stability if costs consistently exceed revenue, we do not know the extent to which this inconsistency might also affect equity in organ procurement or patient access to transplants. We are committed to identifying and addressing Medicare payment inequities for organ acquisition costs in the transplant ecosystem.

Another commenter on the FY 2022 IPPS/LTCH PPS proposed rule suggested that the contractor review, approve, and publish IOPO non-renal SACs to provide needed oversight. We responded that we would consider our options for future rulemaking (86 FR 73479). We believe it is important that IOPOs continue their responsibility for establishing their non-renal SACs to maintain financial stability and control over their operating revenue and cash flow, which is based upon the SACs they bill (42 U.S.C. 273(b)); however, requiring reconciliation and settlement of IOPOs' non-renal organ acquisition costs would provide needed contractor review to ensure alignment with Medicare's reasonable cost principles while still encouraging IOPOs' fiscal responsibility.

Our authority to reconcile and settle non-renal organ acquisition costs exists under section 1138(b) of the Act. Medicare payment for organ procurement costs may be made only if an OPO has been designated by the Secretary as the OPO for its service area (§ 486.301(a)(1)). An OPO must enter into an agreement with CMS in order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid (§ 486.304(c)). Consequently, all OPOs wishing to receive Medicare and Medicaid reimbursement for the procurement of organs must have a signed agreement with CMS.[308]

For these reasons, we are considering a potential policy approach under which Medicare would reconcile and settle for its share of an IOPO's non-renal organ acquisition costs, in accordance with section 1861(v) of the Act and §§ 413.60 and 413.64(f). Under this potential policy approach, Medicare-certified IOPOs would submit a Medicare cost report for review, reconciliation, and settlement of non-renal organ acquisition costs to determine Medicare's reasonable costs. This potential policy approach would mirror our current approach for determining Medicare's reimbursement of IOPOs' kidney acquisition costs. In addition, as part of this potential policy approach, we would require IOPOs to provide their non-renal SACs to the contractor, similar to how IOPOs are currently required to share their renal SACs with the contractor (*see* § 413.420(d)(4)). This potential policy approach that we are considering would provide needed contractor oversight to protect the Medicare Trust Fund and the transplant ecosystem, and would ensure that non-renal organ acquisition costs are paid on a reasonable cost basis. Such an approach would promote fiscal responsibility for IOPOs, and would also create a more equitable, consistent process for billing and reimbursing organ acquisition costs for non-renal versus renal organs. We are requesting information on the alternative policy approach under consideration, and on the following questions:

1. Does the current policy of not reconciling and settling IOPOs' non-renal organ acquisition charges lead to excessive non-renal SACs? If yes, please explain.

2. How often and to what extent do IOPOs have non-renal organ acquisition costs that exceed the revenue they receive for those non-renal organs procured? Are there particular situations or items or services where an IOPO's non-renal organ costs would exceed the non-renal SAC amount received from the TH (or other IOPO) for the organ(s) procured?

3. Does the current lack of reconciliation and settlement of non-renal organ acquisition costs disincentivize IOPOs from procuring non-renal organs? Does it create an inequity in organ procurement for renal vs. non-renal organs? Would a potential policy approach that included a requirement to reconcile and settle non-renal organ acquisition costs better support the transplant ecosystem?

4. How would contractor review, reconciliation, and settlement of IOPOs' non-renal organ acquisition costs affect the transplant ecosystem? Would there be any effect on those waiting for a non-renal transplant or on transplant hospitals?

5. Would CMS's adoption of a policy approach that required reconciliation and settlement of non-renal organ acquisition costs cause IOPOs to procure fewer organs, more organs, or about the same number of organs for transplant? If so, how and why?

[308] See form CMS 576–A, expires January 31, 2023; OMB No. 0938–0512.

XVIII. Rural Emergency Hospitals (REH): Payment Policies, Conditions of Participation, Provider Enrollment, Use of the Medicare Outpatient Observation Notice, and Physician Self-Referral Law Updates

A. Rural Emergency Hospitals (REH) Payment Policies

1. Introduction

Americans who live in rural areas of the nation make up about 20 percent of the United States (U.S.) population, and they often experience shorter life expectancy, higher all-cause mortality, higher rates of poverty, fewer local doctors, and greater distances to travel to see health care providers, compared to their urban and suburban counterparts.[309] In addition, one in five rural residents identifies as Black, Hispanic, American Indian/Alaska Native (AI/AN), Asian American/Pacific Islander (AA/PI), or a combination of ethnic backgrounds. Compared to the non-Hispanic White rural population, these rural minority groups often and regularly experience several disadvantageous social determinants of health.[310]

The health care inequities that many rural Americans face raise serious concerns that the trend for poor health care access and worse outcomes overall in rural areas will continue unless the potential causes of such health care inequities are addressed.

There have been growing concerns over the closures of rural hospitals and critical access hospitals (CAHs). Between 2010 and February 2022, 138 rural hospitals stopped providing inpatient services, 44 of which were Critical Access Hospitals. There were 75 complete hospital closures where all services ended and 63 hospital conversions where inpatient services ended but some type of health care service continued.[311] Rural hospitals report they continue to face the threat of closure because they lack sufficient patient volume to offer traditional hospital inpatient acute care services required for Medicare payment; however, the demand still exists for emergency and outpatient services in areas served by these hospitals. Rural hospitals are essential to providing health care to their communities and the closure of these hospitals limits access to care for the communities they once served and reduces employment opportunities, further impacting local economies. Barriers such as workforce shortages can impact health care access in rural communities and can lead to unmet health needs, delays in receiving appropriate care, inability to get preventive services, financial burdens, and preventable hospitalizations.[312]

The Consolidated Appropriations Act (CAA), 2021, was signed into law on December 27, 2020. In this legislation, Congress established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). These providers will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals may convert to REHs if they were CAHs or rural hospitals with not more than 50 beds participating in Medicare as of the date of enactment of the CAA.

REHs are expected to help address the barriers in access to health care, particularly emergency services and other outpatient services that result from rural hospital closures, and by doing so, may help address observed inequities in health care in rural areas.

On January 20 and 21, 2021, President Biden issued three executive orders related to issues of health equity: Executive Order 13985 ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government;'' [313] Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation;'' [314] and Executive Order 13995 ''Ensuring an Equitable Pandemic Response and Recovery.'' [315]

Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' requires the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality by recognizing and working to redress inequities in its policies and programs that serve as barriers to equal opportunity. In accordance with this executive order, persons who live in rural areas are identified as belonging to underserved communities that have been adversely affected by inequality.

Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation'' requires the Federal Government to prevent and combat discrimination, including when accessing health care, on the basis of gender identity or sexual orientation, and to fully enforce Title VII of the Civil Rights Act. This executive order also requires the Federal Government to fully enforce other laws that prohibit discrimination on the basis of gender identity or sexual orientation, all of which impact all persons, including those in rural communities.

In accordance with Executive Order 13995, ''Ensuring an Equitable Pandemic Response and Recovery,'' the Federal Government must identify and eliminate health and social inequities resulting in disproportionately higher rates of exposure, illness, and death related to COVID–19 and take swift action to prevent and remedy differences in COVID–19 care and outcomes within communities of color and other underserved populations. The executive order highlights the observed inequities in rural and Tribal communities, territories, and other geographically isolated communities. We believe the services furnished by REHs, could be one means of addressing some of the issues raised in these orders, particularly, barriers to access health care in rural communities.

Consistent with these executive orders, in implementing the new REH provider type, we are committed to advancing equity for all, including racial and ethnic minorities, members of the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) community, people with limited English proficiency, people with disabilities,

[309] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[310] Health Resources & Services Administration (2021). Rural Hospital Programs. *https://www.hrsa.gov/rural-health/rural-hospitals/.*

[311] UNC: Cecil G. Sheps Center for Health Services Research. (2022). Rural Hospital Closures. *https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.*

[312] Healthy People 2020 (n.d.) Access to Health Services. *https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services.*

[313] The White House. (2021). Briefing Room: Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-andsupport-for-underserved-communities-through-thefederal-government/.*

[314] The White House. (2021). Briefing Room: Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-preventing-and-combatingdiscrimination-on-basis-of-gender-identity-orsexual-orientation/.*

[315] The White House. (2021). Briefing Room: Executive Order on Ensuring an Equitable Pandemic Response and Recovery. *https://www.whitehouse.gov/briefing-room/presidentialactions/2021/01/21/executive-order-ensuring-anequitable-pandemic-response-and-recovery/.*

rural populations, and people otherwise adversely affected by persistent poverty or inequality.

2. Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type

Section 125 of Division CC of the CAA was signed into law on December 27, 2020 and establishes REHs as a new Medicare provider type. Section 125 of the CAA added section 1861(kkk) to the Social Security Act (the Act), which sets forth the requirements for REHs. Section 1861(kkk)(2) of the Act defines an REH as a facility that is enrolled in the Medicare program as an REH; does not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements of a staffed emergency department; meets staff training and certification requirements established by the Secretary of the Department of Health and Human Services (the Secretary); and meets certain conditions of participation (CoPs) applicable to hospital emergency departments and CAHs with respect to emergency services.

Additionally, section 125(a)(1) of the CAA added section 1861(kkk)(1) of the Act, which requires that REHs provide emergency department services and observation care and, at the election of the REH, other medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking. The REH must also have a staffed emergency department 24 hours a day, 7 days a week, have a physician, nurse practitioner, clinical nurse specialist, or physician assistant available to furnish rural emergency hospital services in the facility 24 hours a day, and meet applicable staffing requirements similar to those for CAHs.[316]

In order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of enactment of the CAA, 2021 (December 27, 2020), was a CAH or a rural hospital with not more than 50 beds. For the purpose of REH designation, section 1861(kkk)(3)(B) defines rural hospital as a subsection (d) hospital (as defined in section 1886(d)(1)(B) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act)), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. In addition, the REH must meet certain other requirements under section 1861(kkk) of the Act, including, but not limited to the following:

- An annual per patient average of 24 hours or less in the REH;
- Staff training and certification requirements established by the Secretary;
- Emergency services CoPs applicable to CAHs;
- Hospital emergency department CoPs determined applicable by the Secretary;
- The applicable SNF requirements (if the REH includes a distinct part SNF);
- A transfer agreement with a level I or level II trauma center; and
- Any other requirements the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services by an REH.

Starting on January 1, 2023, an REH that provides rural emergency hospital services (as defined in section 1861(kkk)(1) of the Act) will receive a Medicare payment for those services pursuant to section 1834(x)(1) of the Act, as added by section 125 of the CAA, that is equal to the amount of payment that would otherwise apply under the Medicare Hospital Outpatient Prospective Payment System (OPPS) for covered outpatient department (OPD) services increased by 5 percent. The beneficiary co-payments for these services will be calculated the same way as under the OPPS for the service, excluding the 5 percent payment increase. In addition, section 1834(x)(2) of the Act provides an additional monthly facility payment to an REH.

To participate in the Medicare program and receive payment for services furnished to Medicare beneficiaries, providers of services such as hospitals, home-health agencies, hospices, SNFs, and now REHs must enter into a provider agreement with CMS, in accordance with section 1866 of the Act. Medicaid providers, likewise, must enter into provider agreements with State Medicaid agencies to be eligible for participation in that program as described in section 1902(a)(27) of the Act. By entering into a provider agreement, a facility agrees that it will comply with the applicable requirements of the Medicare and Medicaid statutes and the regulations that the Secretary issues under the respective statute.

Section 1861(kkk)(7) of the Act requires the Secretary to establish quality measurement reporting requirements for REHs, which may include claims-based outcome measures and/or patient experience surveys. An REH must submit quality measure data to the Secretary with respect to each year beginning in 2023 (or each year beginning on or after the date that is one year after one or more measures are first specified), and the Secretary is required to establish procedures to make the data available to the public on the CMS website. At this time, CMS is requesting information on certain quality measures and quality reporting requirements for REHs as discussed further in section XVI of this proposed rule.

The Quality Improvement Organization requirements of the Act shall apply to REHs in the same manner that they apply to hospitals and CAHs, in accordance with section 1866(a) of the Act (as amended by section 125(b)(1) of the CAA). In addition, the requirements established at section 1864 of the Act for hospitals and CAHs to be surveyed for compliance with the CoPs shall apply to REHs in the same manner as other hospitals and CAHs, in accordance with section 125(d)(2) of the CAA.

In accordance with section 1864 of the Act, CMS uses State surveyors to determine whether a provider or supplier subject to certification qualifies for an agreement to participate in Medicare. Additionally, under section 1865 of the Act, some providers or suppliers subject to certification have the option to instead elect to be accredited by private accrediting organizations (AOs) whose Medicare accreditation programs have been approved by CMS as having standards and survey procedures that meet or exceed all applicable Medicare requirements. The survey process for Medicare and Medicaid participating providers and suppliers provides an opportunity for these providers and suppliers to demonstrate compliance with all of the applicable CoPs, conditions for coverage (CfCs) or requirements. The methods used by CMS to determine compliance with the regulations include surveys conducted by a State survey agency, surveys conducted by AOs that have deeming authority for Medicare providers and suppliers, and self-attestation. CMS would require REHs participating in Medicare to demonstrate and maintain compliance with the provisions included in the CY 2023 OPPS final rule with comment period.

[316] Congress.gov. (2020). H.R.133—Consolidated Appropriations Act, 2021. *https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf.*

3. Summary of Comments by Interested Parties in Response to REH Request for Information

In preparation for developing these proposed standards and to gain a clear understanding of the challenges faced by facilities providing health care services in rural communities, we published a Request for Information (RFI) on REHs in the proposed rule, ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals'' (86 FR 42018) on August 4, 2021. CMS sought public input on a broad range of issues to inform our policymaking in establishing this new provider type. The RFI solicited public input on the concerns of rural providers, including in the areas of health and safety standards, health equity, payment policies, quality measures and quality reporting, and additional considerations and unintended consequences that should be considered during the development of standards for REHs.

Commenters on the RFI generally noted that CMS should take into consideration the challenges associated with the provision of health care services in rural communities. Some commenters noted that, while Congress did not specify the exact steps that CMS should take to calculate the annual facility payment, CMS should do so in a manner that maximizes potential payment to REHs to ensure these hospitals can continue to operate. Other commenters cautioned CMS against calculating the monthly facility payment in a way that leads to excessive payment. Commenters also encouraged CMS to set forth the details of the payment calculation in rulemaking, so that interested parties could replicate the calculation. With regard to the services provided by REHs, commenters recommended that REHs should provide maternal health, behavioral/mental health services, and telehealth services to further support the communities that they will serve. Commenters recommended that CMS pay for all REH services at the OPPS rate plus 5 percent. A few commenters also suggested that CMS should pay for all services furnished by an REH, including those that are not designated as REH services, at the applicable rate plus 5 percent. With regard to health equity, several interested parties commented that REHs could have significant value for underserved, rural populations by maintaining local access to care, reducing travel times for care, and serving as leaders for community health improvement efforts including efforts to address the social determinants of health. We note that CMS is committed to reducing inequities in rural communities and we are considering the best approach to address health equity in the standards for all Medicare and Medicaid participating providers and suppliers, including REHs.

We have reviewed all comments from interested parties and have taken them into consideration while drafting this proposed rule. We appreciate the interested parties' input and responses to our outreach efforts thus far.

During the development of the policies to implement this new provider type, we reviewed the public comments received on the REH RFI, and held public listening sessions with national stakeholder organizations as well as tribal communities. We also gave presentations at CMS' hospital, rural health, and SNF open door forums and sought public feedback.

4. Payment for Services Performed by REHs

a. Covered Outpatient Department (OPD) Services Performed by REHs

(1) Defining ''REH Services''

Section 1861(kkk)(1)(A) defines the term ''REH services'' as emergency department and observation services as well as, at the election of the REH, other medical and health services furnished on an outpatient basis as specified by the Secretary through rulemaking.

We considered how to determine what other covered outpatient medical and health services should be considered ''REH services'' for purposes of payment under section 1834(x)(1). Section 1834(x)(1) provides that the amount of payment for REH services shall be equal to the amount of payment that would otherwise apply under section 1833(t) of the Act for covered OPD services (as defined in section 1833(t)(1)(B) (other than clause (ii) of such section, which are inpatient hospital services paid under the OPPS)), increased by 5 percent. We interpret this statutory language to mean that the scope of covered OPD services as defined in 1833(t)(1)(B) of the Act (excluding 1833(t)(1)(B)(ii)) represents the outer limit of services that CMS may specify as ''REH services.'' 1834(x)(1) frames the services that may receive the 5 percent increase provided under the statute for ''REH services'' exclusively in terms of covered OPD services, which we believe precludes including any services that are not ''covered OPD services'' in this definition. Although we interpret 1834(x)(1) to limit the potential scope of REH services to what is included within the definition of ''covered OPD services,'' we are not suggesting that REHs would be unable to furnish, and receive payment for, other services. Rather, we are stating that only services that are covered OPD services can be paid as specified under Section 1834(x)(1). For further discussion of CMS's proposals pertaining to payment for other services performed by REHs, please see discussion in the below section titled ''Services performed by REHs that are not specified REH services.''

Within the universe of covered OPD services, in its broadest interpretation, ''REH services'' could be defined to encompass all services included in the definition of ''covered OPD services,'' as provided in section 1833(t)(1)(B) of the Act, when furnished by an REH, with the exception of services described in clause (ii) of such section, which are hospital inpatient services, as REHs are precluded by section 1861(kkk)(2)(B) of the Act from providing acute inpatient services. Alternatively, CMS could define ''REH services'' to include only a smaller subset of services. For instance, we considered limiting ''REH services'' to services that are emergent in nature, such as those services described by the specific HCPCS codes describing emergency department visits and observation services.

We have some concerns, however, about narrowly defining the covered OPD services for which REHs may receive payment as REH services to only services that are emergent in nature. For one, if CMS were to limit the definition of REH services to strictly emergency services, this might cause REHs to cease to furnish other covered OPD services previously provided by the facility upon conversion of the facility to an REH, which could limit access to such services for some beneficiaries. This would seem antithetical to the purpose of section 125 of the CAA, which was created with the goal of ensuring greater access to outpatient services in rural areas. Further, a narrower definition could exclude services that may be desirable for REHs to provide in order to expand or maintain access to outpatient services in rural areas, including behavioral health, routine imaging, or clinic visits.

In light of our concerns with narrowly defining ''REH services'' and our interest in allowing maximum flexibility for REHs to tailor the services provided to the needs of their individual communities, for purposes of payment, we are proposing to define ''REH

services,'' at 42 CFR 419.91, as all covered outpatient department services, as defined in section 1833(t)(1)(B) of the Act, excluding services described in section 1833(t)(1)(B)(ii), furnished by an REH that would be paid under the OPPS when provided in a hospital paid under the OPPS for outpatient services, provided that the REH meets the various applicable REH CoPs. In other words, all services that are paid under the OPPS when furnished in an OPPS hospital, with the exception of acute inpatient services, would be REH services when furnished in a REH. We note that this definition of REH services excludes services described in section 1833(t)(1)(B)(ii) of the Act, which cannot be considered REH services because they are inpatient services, which REHs are not permitted to furnish pursuant to section 1861(kkk)(2)(B) of the Act.

Additionally, we are soliciting comments on whether CMS should adopt a narrower definition of REH services than the definition we are proposing, and if so, how commenters believe we should define these services and what methodology commenters suggest CMS use to determine whether a service meets this definition.

(2) Payment for REH Services

Section 1834(x)(1) of the Act states that payment for REH services ''. . . shall be equal to the amount of payment that would otherwise apply under section 1833(t) for covered OPD services (as defined in section 1833(t)(1)(B) (other than clause (ii) of such section)), increased by 5 percent to reflect the higher costs incurred by such hospitals, and shall include the application of any copayment amount determined under section 1833(t)(8) as if such increase had not occurred.'' As a result, we propose that payments for REH services would be calculated using existing OPPS payment policies and rules. The only differences between the payment for a covered OPD service furnished by an OPPS provider and the payment for an REH service furnished by an REH provider would be that the service payment to the REH would be equal to the applicable OPPS payment for the same service plus an additional 5 percent. Accordingly, we propose to codify, at 42 CFR 419.92(a)(1), that the payment rate for an REH service would be calculated using the OPPS prospective payment rate for the equivalent covered OPD service increased by 5 percent.

Because we are proposing to utilize OPPS payment policies and rules to effectuate payment rates for REH services equivalent to the OPPS payment rates plus five percent, we believe it would be most efficient from a claims processing perspective for the REHs to utilize the OPPS claims processing system to process REH payments. We propose updating the OPPS claims processing logic to include an REH-specific payment flag, which an REH provider would utilize to indicate that the provider is an REH and should not be paid at the OPPS payment rates, but should instead be paid at the REH payment rates. Claims from REH providers for REH services would be processed within the OPPS claims processing system. However, when a REH submits a facility claim with the REH-specific payment flag, this payment flag would trigger payment for REH services on the claim at the REH services payment rate, which is the OPPS payment rate plus 5 percent.

We also propose, consistent with the requirement in section 1834(x)(1) of the Act, that the copayment amount for a REH service would be determined as if the 5 percent payment increase had not occurred. That is, the additional 5 percent payment for REH services, above the amount that would be paid for covered OPD services, would not be subject to a copayment. Therefore, we propose to codify in the REH payment regulation, at 42 CFR 419.92(a)(2), that the beneficiary copayment amounts for REH service would be the amounts determined under the OPPS for the equivalent covered OPD service, pursuant to section 1833(t)(8) of the Act, and would exclude the 5 percent payment increase that applies to the REH service payment.

Finally, we note that section 1834(x)(5)(A) of the Act states that ''. . . except as provided in subparagraph (B), payments under this subsection shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841.'' The statute makes clear that payments for services rendered by REHs receive payment from the Federal Supplementary Medical Insurance Trust Fund under section 1841. We note, however, that payments for REH services would have no impact on OPPS budget neutrality because REH services are not covered OPD services under section 1833(t) of the Act to which the OPPS budget neutrality requirements apply. This also means that REH claims would not be used for OPPS rate setting purposes. Consistent with section 1834(x)(5)(A) of the Act, REH service payments will be paid from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Act.

b. Services Performed by REHs That Are Not Specified REH Services

Section 1834(x)(1) specifically addresses the payment rate that applies for ''REH services,'' which, as discussed above, include at most the full range of covered OPD services for which payment can be made under the OPPS. Likewise, as discussed further below, sections 1834(x)(3) and 1834(x)(4) of the Act specifically address payment for ambulance services and post-hospital extended care services that are furnished by an REH. However, section 125 of the CAA is silent on how CMS should pay for other services furnished by an REH, such as services paid under the Clinical Laboratory Fee Schedule (CLFS) or outpatient therapy services, that may be provided on an outpatient basis by hospital outpatient departments, but that are not covered OPD services, as defined under section 1833(t)(1)(B) of the Act, and thus, pursuant to the limiting language in 1834(x)(1) of the Act, would not be payable as REH services when furnished by an REH.

In order for a REH to fulfill the statutory requirements set forth in section 1861(kkk)(2) of the Act, as well as the proposed CoPs for REHs described in the proposed rule ''Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospital (REH) and Critical Access Hospital CoP Updates,'' which appeared in the **Federal Register** on July 6, 2022 (87 FR 40350), REHs must be capable of providing certain types of outpatient services that are not covered OPD services, such as basic laboratory services and certain diagnostic services. Additionally, the proposed REH CoPs state that the REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services.

As discussed above, section 1834(x)(1) of the Act provides that the amount CMS shall pay for REH services furnished by an REH shall be the same amount that would otherwise apply under section 1833(t) of the Act for covered OPD services plus five percent. However, section 125 of the CAA does not indicate that the additional 5 percent payment described in 1834(x)(1) of the Act would apply to any services other than those within the definition of ''REH services.'' While some of the

services described by the proposed REH CoPs would meet the definition of an REH service because they are also covered OPD services under section 1833(t)(1)(B) of the Act and would therefore be eligible for the 5 percent additional payment specified in 1834(x)(1) of the Act, others—such as laboratory services paid off of the CLFS, and outpatient rehabilitation services—are outside the scope of covered OPD services and therefore, for the reasons previously discussed, could not meet the definition of a REH service. However, CMS believes that it is consistent with the statutory requirements for rural emergency hospitals set forth in section 1861(kkk)(2) of the Act for these services to be paid when they are furnished in an REH. As a result, we are proposing that any outpatient service furnished by an REH consistent with the statutory requirements governing this provider type and the proposed REH CoPs, that does not meet the proposed definition of REH services, would be paid at the same rate the service would be paid if performed in a hospital outpatient department and paid under a fee schedule other than the OPPS, provided the requirements for payment under that system are met.

As noted above, section 1834(x)(3) of the Act states that ''. . . for provisions relating to payment for ambulance services furnished by an entity owned and operated by a rural emergency hospital, see section 1834(l).'' Section 1834(l) of the Act establishes the Medicare ambulance fee schedule. Therefore, consistent with section 1834(x)(3) of the Act, we propose to codify, at 42 CFR 419.92(c)(1), that an entity that is owned and operated by an REH that provides ambulance services will receive payment for such services under the ambulance fee schedule as described in section 1834(l) of the Act and, as described in section VIII.A.7.b of this proposed rule, to revise § 410.40(f) to include an REH as a covered origin and destination for ambulance transport.

Section 1861(kkk)(6)(A) of the Act provides discretion for REHs to include a unit that is a distinct part of the facility licensed as a skilled nursing facility to furnish post-hospital extended care services. Further, section 1834(x)(4) of the Act states that ''. . . for provisions relating to payment for post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility, see section 1888(e).'' Section 1888(e) of the Act establishes the skilled nursing facility prospective payment system. Consistent with section 1834(x)(4), we therefore propose to codify, at 42 CFR 419.92(c)(2), that post-hospital extended care services provided by an REH in such a unit receive payment through the skilled nursing facility prospective payment system as described at section 1888(e) of the Act.

c. Payment for an Off-Campus Provider-Based Department of an REH

As discussed above, section 1834(x)(1) of the Act sets forth the amounts that shall be paid for REH services in terms of amounts that would be otherwise apply for ''covered OPD services'' under 1833(t). Section 1833(t)(1)(B)(v) of the Act, which was added by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, (''BBA''), specifically excludes from the definition of ''covered OPD services'' applicable items and services furnished by an off-campus outpatient department of a provider as defined by sections 1833(t)(21)(A) and (B) of the Act. In light of the exclusion contained in 1833(t)(1)(B)(v) of the Act, CMS has carefully considered how an REH will be paid for items and services furnished by in an off-campus outpatient department of the REH. Section 1861(kkk)(8) of the Act appears to speak to this issue, stating that nothing in that provision, section 1833(a)(10), or section 1834(x) shall affect the application of paragraph (1)(B)(v) of section 1833(t), relating to applicable items and services (as defined by 1833(t)(21)(A)) that are furnished by an off-campus outpatient department of a provider (as defined by 1833(t)(21)(B)). For the reasons discussed in this section, CMS is proposing to interpret this language as stipulating that the new provisions governing payments for services furnished by REHs are not intended to change the existing scope and applicability of the section 603 amendments to section 1833(t) of the Act, and that, as a result, the section 603 amendments would not apply to the determination of the payment rates for services furnished by an off-campus outpatient department of a REH.

Section 603 of the BBA amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of ''covered OPD services'' applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider, as defined in paragraph (21)(B) of the section. Section 603 also added a new paragraph (21) to section 1833(t) of the Act, which defines the terms ''applicable items and services'' and ''off-campus outpatient department of a provider,'' and requires the Secretary to make payments for such applicable items and services furnished by an off-campus outpatient department of a provider under an applicable payment system (other than the OPPS). In defining the term ''off-campus outpatient department of a provider,'' section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015) that is not located on the campus (as defined in § 413.65(a)(2)) of the provider, or within the distance (as described in the definition of campus) from a remote location of a hospital facility (as defined in section § 413.65(a)(2)). We note that, in order 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. Accordingly, in this proposed rule, we refer to an ''off-campus outpatient department of a provider,'' which is the term used in section 603, as an ''off-campus outpatient provider-based department'' or an ''off-campus PBD.''

Sections 1833(t)(21)(B)(ii) through (vi) of the Act except from the definition of ''off-campus outpatient department of a provider,'' for purposes of paragraphs (1)(B)(v) and (21)(B) of the section, an off-campus PBD that was billing under section 1833(t) of the Act with respect to covered OPD services furnished prior to November 2, 2015, as well as off-campus PBDs that meet the ''mid build'' requirement described in section 1833(t)(21)(B)(v) of the Act and the departments of certain cancer hospitals. Likewise, the department of a provider located on the campus of such provider or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility (as defined in § 413.65(a)(2)), is also excepted from the definition of ''off-campus outpatient department of a provider'' pursuant to section 1833(t)(21)(B)(i). The items and services furnished on or after January 1, 2017 (or during 2018 or a subsequent year for off-campus PBDs that qualify for the mid-build exception), by the various types of excepted off-campus PBDs described in 1833(t)(21)(B) continue to be paid under the OPPS. In addition, we note that in defining ''applicable items and services,'' section 1833(t)(21)(A) of the Act specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79720), we established a number of policies to implement the section 603 amendments. Broadly, we: (1) defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. We specified the Medicare Physician Fee Schedule (PFS) as the applicable payment system for most nonexcepted items and services furnished by nonexcepted off-campus PBDs. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (82 FR 53030).

Section 125(a)(1) of the CAA added the following language, at section 1861(kkk)(8) of the Act, regarding the application of the section 603 amendments to REHs:

''(8) CLARIFICATION REGARDING APPLICATION OF PROVISIONS RELATING TO OFF–CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—Nothing in this subsection, section 1833(a)(10), or section 1834(x) shall affect the application of paragraph (1)(B)(v) of section 1833(t), relating to applicable items and services (as defined in subparagraph (A) of paragraph (21) of such section) that are furnished by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).''

While we are proposing to define REH services as the covered OPD services furnished by an REH, REHs are not paid under the OPPS; we do not interpret the language in section 1861(kkk)(8) to indicate that the section 603 amendments to section 1833(t) should apply to off-campus PBDs of a REH. Rather, we believe section 1861(kkk)(8) can reasonably be interpreted as demonstrating an intent that the creation of the REH provider type would not change the existing scope and applicability of the section 603 amendments, such that the exclusion of items and services furnished by non-excepted off-campus PBDs from the definition of covered outpatient department services under the section 603 amendments continues to apply only to items and services furnished by the non-excepted off-campus PBDs of subsection (d) hospitals paid under the OPPS and does not apply to items and services furnished by an off-campus PBD of an REH, because REHs are a different provider type and are not paid under the OPPS.

We note that interpreting section 1861(kkk)(8) of the Act to instead mean that the section 603 amendments should apply to items and services furnished by off-campus PBDs of REHs appears to be contrary to the Congressional intent for creating this new provider type, as this interpretation would potentially disincentivize some otherwise eligible facilities from choosing to convert to REHs. Specifically, we note that section 603 does not apply to items and services furnished by the off-campus PBDs of CAHs. However, if the section 603 amendments applied to the off-campus PBDs of a former CAH that becomes an REH, these off-campus PBDs would appear to meet the statutory definition of ''off-campus outpatient department of a provider,'' and items and services furnished by these entities would be excluded from the definition of ''covered OPD services'' and paid at the alternative applicable payment system as provided under section 1833(t)(21)(C). Thus, if a CAH becomes an REH and as a result becomes subject to the section 603 amendments, it would experience a significant decrease in payment for items and services furnished by its off-campus PBDs, relative to the amount paid for such services when the entity was a CAH (where it is generally paid at 101 percent of reasonable cost). This would create a financial disincentive for CAHs to convert to REHs and would seem to be contrary to the Congressional intent for creating this new provider type.

We propose to codify in the REH payment regulation, at 42 CFR 419.93(a), that items and services furnished by off-campus PBDs of REHs are not applicable items and services under sections 1833(t)(1)(B)(v) or (t)(21) of the Act, and thus that items and services furnished by these off-campus PBDs that otherwise meet the definition of ''REH services'' will receive the REH services payment amount of the OPPS payment plus 5 percent, as provided in section 1834(x)(1) of the Act and described in the proposed regulation text at 42 CFR 419.92(a)(1). Likewise, items and services furnished by the off-campus PBD of a REH that do not meet the definition of ''REH services'' would be paid under the payment system applicable to that item or service, provided the requirements for payment under the relevant system are met, as described in the proposed regulation text at 42 CFR 419.92(c).

We seek comment on alternative payment approaches for items and services furnished by the off-campus PBDs of REHs that may be supported by the REH statute, including section 1861(kkk)(8). For example, CMS seeks comment on whether application of the section 603 amendments to an off-campus PBD of an REH should depend on whether that provision applied to the entity before it converted to an REH. Under that framework, if a CAH converts to a REH, because section 1833(t)(1)(B)(v) did not apply to the CAH before converting, REH services furnished by any existing off-campus PBDs of the CAH would be paid at 105 percent of the OPPS rate, rather than at the PFS-equivalent rate required by section 1833(t)(1)(B)(v) and (t)(21). However, because sections 1833(t)(1)(B)(v) and (t)(21) would have applied to any non-excepted off-campus PBDs of small rural hospital paid under the OPPS before that entity converted to an REH, any existing non-excepted off-campus PBDs of the small rural hospital would continue to be considered non-excepted off-campus PBDs and would continue to receive the PFS-equivalent rate under section 1833(t)(21)(C). Under this framework, any new off-campus PBDs created by the REH would be subject to the section 603 amendments. We are seeking comment on our proposed approach for paying for items and services furnished by the off-campus PBDs of REHs, as well as any alternative approaches to this issue that interested parties may have.

5. Monthly REH Facility Payment

a. Overview of the Monthly REH Facility Payment

Section 1834(x)(2) of the Act establishes an additional facility payment that is paid monthly to an REH. Section 1834(x)(5)(B) specifies that this monthly facility payment shall be made from the Federal Hospital Insurance Trust Fund under section 1817. Sections 1834(x)(2)(B) and 1834(x)(2)(C) of the Act require that, for 2023, the monthly payment is determined by first calculating the total amount that CMS determines was paid to all CAHs under Title 18 of the Act in 2019 minus the estimated total amount that would have been paid under Title 18 to CAHs in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility

services under the applicable prospective payment systems for such services during 2019. The difference is divided by the number of CAHs enrolled in Medicare in 2019 to calculate the annual amount of this additional facility payment per individual REH for 2023. The annual payment amount is then divided by 12 to calculate the monthly facility payment that each REH will receive. For 2024 and subsequent years, the monthly facility payment will be the amount of the monthly facility payment for the previous year increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

We interpret the references to the year 2019 in sections 1834(x)(2)(C)(i) and 1834(x)(2)(C)(ii) of the Act to mean calendar year 2019 (CY 2019) rather than fiscal year 2019 (FY 2019) because, in the absence of language implicitly or explicitly denoting the year as fiscal, we believe calendar year is the most logical reading. The REH payment system is based on the OPPS, which sets its payment rates and rules on a CY schedule. Additionally, section 1834(x)(1) of the Act states that payments for REH services will begin on January 1, 2023, which is the first day of the CY. Accordingly, we propose to codify the calculation of the REH monthly facility payment, under 42 CFR 419.92(b)(1), to specifically refer to the amounts that were and would have been paid to CAHs in calendar year 2019. Under this proposal, we would apply the CY schedule even when the sections refer to the inpatient hospital prospective payment system or the skilled nursing facility prospective payment system where substantial policy changes are implemented on a fiscal year schedule. Therefore, when we calculate the total amount that would have been paid to CAHs if inpatient hospital services, outpatient hospital services, and skilled nursing facility services were paid under their respective prospective payment systems, we would use claims data from the last nine months of FY 2019 and the first three months of FY 2020 to calculate payment data for CY 2019 for both inpatient hospital services and skilled nursing facility services and claims data from CY 2019 for outpatient hospital services.

When determining ''the total amount that . . . was paid under this title to all critical access hospitals,'' as described in section 1834(x)(2)(C)(i)(I) of the Act, we propose to include both amounts paid to CAHs from the Medicare program and from beneficiary copayments. Likewise, we propose to include both projected payments from the Medicare program and projected beneficiary copayments when determining the estimated total amount that would have been paid to CAHs had they been paid on a prospective basis, as described in section 1834(x)(2)(C)(i)(II). By including both Medicare trust fund payments and beneficiary copayments, we believe that the resulting calculations will reflect the actual payments CAHs received for services provided in CY 2019 and ensure that the full amount of additional payments made to CAHs are reflected in the determination of the monthly REH facility payment. Because CAHs are generally paid at 101 percent of reasonable cost, a 2014 report found that in 2012 beneficiary copayments consisted of around 47 percent of the total Medicare-related spending for CAHs.[317]

Excluding around 47 percent of the payment CAHs received in 2019 for Medicare services from the REH monthly facility payment calculation would generate a monthly facility payment that would cover a substantially smaller share of the costs REHs face. We believe that if the calculation of the monthly facility payment does not reflect payments from beneficiaries, CAHs and small rural hospitals could be discouraged from converting into REHs because the monthly facility payment would be too small.

Using our calculations, which we will discuss in more detail in sections XVIII.A.5.b and XVIII.A.5.c of this proposed rule, we have determined that the estimated prospective payment for CAHs in 2019 is 58.2 percent of total CAH spending in 2019 when copayments are included for both total CAH spending and the estimated prospective payment for CAHs. The aggregate REH monthly facility payment would be 72 percent of the estimated prospective payment for CAHs in 2019. The combination of the estimated prospective payment for CAHs and the aggregate REH monthly facility payment where copayments are included in the calculation for an REH would be close to the amount that REH would have received from Medicare if it had decided to stay as a CAH and not convert to an REH. Therefore, it less likely that a CAH would lose revenue if it converted to an REH in the future, which may encourage a CAH to convert to an REH. If copayments are removed from both the total amount of CAH spending in 2019 and the estimated prospective payment for CAHs in 2019, the aggregate monthly facility payment for all providers only would be 11.1 percent of the estimated prospective payment for CAHs in 2019 where the estimated prospective payment amount includes copayments. That means a CAH converting to an REH would face a substantial reduction in Medicare payment if it converted to an REH. Please review the detailed calculations below:

Step 1: Total estimated CAH spending in CY 2019 with copayments: $12,083,666,636
- Total estimated prospective payment for CAHs in CY 2019 with copayments: $7,033,248,418
- Difference: $12,083,666,636 − $7,033,248,418 = $5,050,418,218
- Aggregate REH monthly facility payment with copayments: $5,050,418,218
- Share of the aggregate REH monthly facility payment with copayments of the total estimated prospective payment for CAHs in CY 2019 with copayments: $5,050,418,218/$7,033,248,418 = 72 percent

Step 2: Total estimated CAH spending in CY 2019 removing copayments: $12,083,666,636 × 0.53 = $6,404,343,317
- Total estimated prospective payment for CAHs in CY 2019 removing copayments: $5,626,598,734
- Difference: $6,404,343,317 − $5,626,598,734 = $777,744,583
- Aggregate REH monthly facility payment without copayments: $777,744,583
- Total estimated prospective payment for CAHs in CY 2019 with copayments: $7,033,248,418
- Share of the aggregate REH monthly facility payment without copayments of the total estimated prospective payment for CAHs in CY 2019 with copayments: $777,744,583/$7,033,248,418 = 11.1 percent

We believe that including both Medicare trust fund payments and beneficiary copayments in the calculation of the monthly facility payment reflects the intent of the statute to provide incentives for CAHs and small rural hospitals that might otherwise close to convert to REHs and continue to provide outpatient hospital care in rural communities. We propose to codify including payments from the Medicare program and beneficiary copayments for CAHs to calculate the monthly facility payment under 42 CFR 419.92(b)(1)(i) and (ii).

[317] Office of Inspector General, Department of Health and Human Services. 2014. Medicare beneficiaries paid nearly half of the costs for outpatient services at critical access hospitals. OEI–05–12–00085. Washington, DC: OIG.

Finally, section 1834(x)(2)(D) of the Act states that ''[a] rural emergency hospital receiving the additional facility payment under this paragraph shall maintain detailed information as specified by the Secretary as to how the facility has used the additional facility payments. Such information shall be made available to the Secretary upon request.'' Accordingly, we are proposing to codify this reporting requirement, under 42 CFR 419.92(b)(3), to state that an REH receiving the additional monthly facility payment must maintain detailed information as to how the facility has used the monthly facility payments and must make this information available upon request. We believe that this requirement can be met using existing cost reporting requirements for outpatient hospital facilities that would include REHs. The cost reports track spending on outpatient hospital services as a part of overall provider spending. This information will show if a sufficient share of revenue to the REH, which includes the monthly facility payment, is being directed to outpatient care. For CY 2023, we therefore do not propose to establish any new reporting or data collection requirements for REHs related to their use of the REH monthly facility payments. However, we will monitor this issue in CY 2023 to see if we may need to propose new reporting or data collection requirements for REHs in future rulemaking.

b. Proposed Methodology To Estimate Medicare CAH Spending in CY 2019

Section 1834(x)(2)(C)(i)(I) requires that CMS use ''the total amount that the Secretary determines was paid under this title to all critical access hospitals in 2019'' as part of the calculation used to determine the monthly facility payment that each REH will receive in 2023. Although the statute provides that this amount shall be an amount determined by the Secretary, the statute is silent regarding what data source the Secretary should use in making such determination. We considered whether CAH claims or cost reports would be the most appropriate data source from which to determine the payments made to CAHs in 2019.

Because CAHs are generally paid at 101 percent of their reasonable costs in furnishing services to Medicare beneficiaries and receive an annual cost settlement for all services covered by Medicare, we did not initially believe that CAH claims would reflect all payments that Medicare may have made to CAHs under Title 18 of the Act. We were most concerned about modelling the annual cost settlement using CAH claims data, because the cost settlement is an accounting action that is not linked to payments reported on individual claims. It was not clear how we would identify the payment or recoupment performed for the cost settlement. By contrast, hospital cost reports track not only payments for claims when they are first submitted to Medicare but also track the annual cost settlements made with CAHs. However, some hospital cost report data can take up to 3 years to be received and processed which raises concerns whether the cost report data for CY 2019 is fully complete. We compared our calculation of Medicare CAH spending in CY 2019 using CAH claims data to our calculation of Medicare CAH spending in CY 2019 using CAH cost report data.

We found that CAH claims data reported approximately $450 million more in CAH Medicare spending ($12,083,666,636) compared to CAH cost report data ($11,631,762,706). Also, the CAH claims data identified 42 more CAHs than the CAH hospital cost report data. Both findings indicated that the CAH claims data may have a more complete report of CAH spending than the CAH cost report data. Finally, we would need to use CAH claims data to estimate prospective Medicare spending for CAHs. CAH claims data is the only payment data source that allows service-specific payment rates to be linked to individual services, which is necessary to estimate Medicare prospective spending. When comparing data for two different sets of calculations, it is generally preferred to use the same data source for both calculations unless an alternate source is clearly superior. Since we are using CAH claims data to estimate prospective Medicare spending for CAHs, we determined that CAH claims data are the best available resource to fulfill the requirements of section 1834(x)(2)(C)(i)(I) of the Act to determine the amount of Medicare payments to all CAHs in CY 2019.

We propose to use CAH claims data with service dates in CY 2019 to calculate the actual Medicare spending for CAHs for CY 2019 as required under section 1834(x)(2)(C)(i)(I) of the Act. Our calculation of CAH Medicare spending will include CAH claims data for inpatient hospital services, inpatient rehabilitation services, inpatient psychiatric services, outpatient hospital services, and skilled nursing services including both hospital-based and swing bed services. As discussed above, we interpret the references to the year 2019 in sections 1834(x)(2)(C)(i) of the Act to mean calendar year 2019 (CY 2019) rather than fiscal year 2019 (FY 2019) because, in the absence of language implicitly or explicitly denoting the year as fiscal, we believe calendar year is the most logical reading. Additionally, section 1834(x)(1) of the Act states that payments for REH services will begin on January 1, 2023, which is the first day of the CY. Therefore, we are using CY 2019 CAH claims data to align with our interpretation of the statute that references to the year 2019 are for the calendar year, and to avoid unintended discrepancies by combining calendar year and fiscal year data. Once we identify the claims that we will use for the calculation, we will calculate the total CAH Medicare spending for CY 2019 by getting the total of the provider payment, coinsurance amounts, and deductible amounts for all of the claims. We propose to codify the calculation of total CAH Medicare spending in CY 2019 to create the monthly facility payment for CY 2023 under 42 CFR 419.92(b)(1)(i).

c. Proposed Methodology To Estimate The Projected Prospective Medicare Payment for CAHs for CY 2019

Section 1834(x)(2)(C)(i)(II) of the Act directs CMS to use ''the estimated total amount that the Secretary determines would have been paid under this title to such hospitals in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during such year'' as part of the calculation used to determine the monthly facility payment that each REH will receive in 2023. The statute clearly directs us to use policy and payment rules from the IPPS, the IRF–PPS, the IPF–PPS, the OPPS, and the Skilled Nursing Facility PPS (SNF PPS) as they applied in CY 2019 to determine the projected prospective Medicare payment for CAHs for CY 2019.

To determine the estimated prospective Medicare payment that CAHs would have received for CY 2019, CMS will need to use data reflecting the Medicare-covered services rendered by CAHs in CY 2019. However, the statute does not specify what data source should be used for generating this estimation. We researched this issue and determined that CAH claims would be the only resource available to estimate projected prospective payment as directed by section 1834(x)(2)(C)(i)(II). We are aware of no other data sources that report individual services received by Medicare beneficiaries in CAHs, and the amounts paid to CAHs for those services, that could be used to estimate projected

prospective payment for Medicare CAH services. To estimate Medicare CAH spending if CAHs were paid on a prospective basis, we therefore propose to use CAH claims for inpatient hospital, inpatient rehabilitation, inpatient psychiatric, skilled nursing facilities, and outpatient hospital services. We also propose to include services and items that are paid through other payment subsystems including clinical lab services; physician services; ambulance services; parenteral and enteral nutrition services; durable medical equipment, prosthetics/orthotics; and supplies; and vaccines and Medicare Part B drugs if those services and items are reported on an inpatient CAH claim, an outpatient CAH claim, or a skilled nursing CAH claim. We propose to model prospective Medicare payment for CAHs by processing the CAH claims data through the IPPS, IRF–PPS, IPF–PPS, OPPS, or SNF–PPS in a test environment as appropriate following the detailed methodologies described in either XVIII.A.5.c.(1) for all claims except for skilled nursing facility claims or XVIII.A.5.c.(2) for skilled nursing facility claims.

In response to our request for information in the CY 2022 OPPS/ASC proposed rule which discussed REH payment policies (86 FR 42288 through 42289), MedPAC expressed concerns that, since CAHs are paid based on procedure cost for inpatient hospital services, they have less incentive to fully document a patient's comorbidities than if the inpatient hospital services were paid prospectively where only documented diagnoses can generate payment for a provider. MedPAC was concerned that if the claims used to document CAH inpatient hospital services do not fully report all relevant patient diagnoses, the amount of projected Medicare prospective payment assigned to CAHs under the IPPS could be underestimated, which would cause the monthly REH facility payment to be larger than the amount that would be paid if CMS made this calculation using a projected Medicare prospective payment that more accurately reflected all relevant diagnoses of patients that received inpatient hospital services from CAHs assuming CAHs have the same distribution of reported primary diagnoses as hospitals receiving prospective payment.[318]

However, we have concerns about adopting a methodology that assigns additional diagnoses for CAH inpatient hospital claims so that these claims are consistent with the distribution of reported primary diagnoses for hospitals receiving prospective payment. The relative health levels of CAH patients compared to patients of hospitals receiving prospective payment would be needed to be able to confirm MedPAC's hypothesis that CAH inpatient hospital claims may be missing some primary diagnosis information because the information is not required for CAHs to receive full payment for the services they render.

We do not have immediately available data describing in aggregate whether Medicare patients receiving care at CAHs are healthier, less healthy, or have a similar level of health compared to Medicare patients receiving care in facilities receiving prospective payment. Also, it is not feasible to gather these data before the implementation of the REH provider type. Obtaining such data would likely involve identifying a representative sample of the patients of CAHs and hospitals receiving prospective payment to determine if there are similar or different distributions of patients based on health status, age, income, and race, which is beyond the scope of this rulemaking process. Therefore, when calculating the projected prospective Medicare payment for CAHs, we are not proposing to adjust the distribution of reported primary diagnoses on the CAH inpatient hospital claims to reflect the distribution of reported primary diagnoses for hospitals receiving prospective payment.

Another issue with relying on inpatient hospital and outpatient hospital CAH claims to estimate the prospective Medicare payment that CAHs would have received in CY 2019 is that these claims do not report the Medicare supplemental payments that hospitals receive through the inpatient and outpatient prospective payment systems. Supplemental payments include IPPS new technology payments, outlier claims payments, clotting factor payments, indirect medical education (IME) payments, disproportionate-share hospital (DSH) payments, including uncompensated care payments under section 1886(r) of the Act, low-volume hospital payments, hospital value-based purchasing program (VBP) payments, and hospital readmissions reduction program (HRRP) adjustments. However, to accurately model how much CAHs would have received if they had instead been paid for applicable services under the inpatient and outpatient prospective payment systems, as provided by section 1834(x)(2)(C)(i)(II) of the Act, we must estimate the various supplemental payments that CAHs would have received under these prospective payment systems.

We therefore propose, in addition to medical claims service data, that CAH payment information used to calculate the projected Medicare prospective payment for CAHs include IPPS new technology payments, outlier claims payments in both the IPPS and the OPPS, clotting factor payments, indirect medical education (IME) payments, DSH payments, uncompensated care payments, and low-volume hospital payments. We chose these supplemental payments because these payments are used to determine the payment amount for claims in either the IPPS or the OPPS.

We are able to estimate new technology add-on payments, outlier payments, and clotting factor payments from the existing CAH claims data.

For IME and DSH adjustments, CAHs generally do not have up-to-date entries in the Provider Specific File. Therefore, the IME and DSH adjustments would be almost always zero in the actual calculation. We are estimating an aggregate projected prospective payment amount for CAHs, and therefore, we do not need to calculate IME and DSH for each individual CAH. Instead, we will estimate an aggregate amount of IME and DSH spending for all CAHs. Our approach is the following:

- First, identify all IPPS hospitals that are classified as rural and calculate the average percentage of additional DSH payment and the average percentage of IME payment for these rural hospitals. We use rural IPPS hospitals as a proxy to estimate the percentage of additional DSH payment and the average percentage of IME payment. Rural IPPS hospitals are more likely to have complete and timely data to allow the calculation of DSH and IME payments than CAHs, because rural IPPS hospitals need to report their data to receive payment. CAHs, where all services are paid at 101 percent of cost, do not have an incentive to report data to generate DSH and IME payments.
- Second, for each CAH, find the closest IPPS hospital to that CAH, even if the IPPS hospital is located in an urban area, and link the additional DSH payment percentage and additional IME payment percentage of the nearby IPPS hospital to the CAH.
- Finally, average the overall rural IPPS DSH payment percentage and IME payment percentage with the modelled DSH payment percentage and IME payment percentage for each individual

[318] Medicare Payment Advisory Commission. September 10, 2021. Comment Letter. *https://www.medpac.gov/wp-content/uploads/2021/10/09102021_OPPS_ASC_2022_MEDPAC_COMMENT_SEC.pdf.* Accessed April 4, 2022.

CAH. These individual average additional DSH and IME payments for each CAH can be aggregated to get a national estimate of DSH and IME spending for CAHs.

We will use the methodology described in the CY 2019 IPPS/LTCH PPS final rule to estimate the low-volume hospital adjustment for CAHs (83 FR 41399). For discharges occurring in FYs 2019 through 2022, the low-volume hospital payment adjustment is determined using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges (both Medicare and non-Medicare discharges) to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year.

For uncompensated care payments, we will use a similar approach to the approach we have described earlier in this section for calculating estimated DSH and IME payments for CAHs. The difference will be that, for uncompensated care payments, we will estimate the share of uninsured patients in each CAH receiving uncompensated care based on a nearby IPPS hospital and adjusted by the average share of uncompensated care patients for all rural IPPS hospitals. These calculations will be performed in addition to calculating the percentage of Medicare inpatient days attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI) and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. We will then aggregate the estimated uncompensated care payments for individual CAHs into a national estimate and include that estimate in the CAH estimated projected prospective payment amount.

We also considered modelling hospital value-based purchasing program (VBP) payments, hospital readmissions reduction program (HRRP) adjustments, and hospital-acquired condition (HAC) reduction program. However, we have identified no feasible way to estimate these adjustments for either individual CAHs or for all CAHs in aggregate. These payments are made based on the actions of individual hospitals, and there are no trends regarding these payments based on whether the hospital is located in a rural or urban area or on the size of the hospital. CAHs do not participate in the VBP, HRRP, or HAC reduction program themselves. So, the only way to model these payments would be to identify trends in comparable hospitals. Since there are no payment trends with the VBP, HRRP, and HAC reduction program, we decided to not include these adjustments in the estimate of projected prospective payment for CAHs.

We propose to codify our proposal to estimate the prospective spending for CAHs in 2019 under 42 CFR 419.92(b)(1)(ii).

(1) Detailed Proposed Methodology To Estimate CY 2019 Prospective Payment for CAHs for Inpatient Hospital and Outpatient Hospital Services

This section provides a proposed methodology using inpatient hospital and outpatient hospital CAH claims and estimated supplemental payments to estimate the projected Medicare prospective payment for CAHs for inpatient hospital and outpatient hospital services. For more detailed information regarding the methodology for estimating the projected aggregate prospective payment for inpatient and outpatient CAH services, please refer to the supplementary document ''Calculation of Rural Emergency Hospital (REH) Monthly Additional Facility Payment for 2023'' on the CMS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*).

Step 1: Proposed CAH Inpatient Prospective Payment (IPPS) Calculation

Preparing Inpatient Claims for CAHs

- Identify CAH inpatient hospital claims by using the provider CCN number.
- Exclude Medicare Advantage encounter claims and claims where Medicare is not the primary payer from the analysis file.
- Feed CAH claims through MS–DRG grouper software to assign MS–DRG code. If the DRG code field on the claim is empty, take the grouper-assigned MS–DRG code as input to calculate payment. Otherwise, take the claim MS–DRG code as input.
- Group CAH claims that have the same Provider CCN, Admission Date, and Beneficiary ID combination into inpatient stays.[319] Take the benefit exhaust date (if present and earlier than discharge date) or discharge date of the last claim in the grouping as the discharge date of the stay. Take the calendar year of the stay discharge date as the calendar year of the stay (and claims making up the stay).
- Identify paid CAH stays by checking if there is at least one paid claim (Type-of-Bill not being ''110'') within the stay. The non-paid stays or non-discharging claims will be assigned zero payment, and the discharging claim (last claim) will be assigned total PPS payment for the stay.

Calculating PPS Payment for Each Component

The Medicare PPS payment includes the components described in the following sections.

1. DRG Payment

DRG payment is calculated as the sum of operating base rate and capital base rate multiplied by DRG weight and Transfer Fraction and their respective geographic adjustment factor.

- The *operating* and *capital base rates* and *DRG weight* are taken from the relevant Final Rule/Correction Notice for either FY 2019 or FY 2020;
- *Transfer Fraction* is calculated by the covered days of stay and the Geometric *Mean Length of Stay* of the DRG code, per post-acute-care transfer adjustment policy;
- *Operating geographic adjustment factor* is calculated as the weighted sum of wage index and operation cost-of-living adjustment, the weights being the labor share and one minus labor share;
- *Capital geographic adjustment* for inpatient hospital services is the wage index raised to the power of 0.6848,[320] multiplied by capital cost-of-living adjustment;
- *Wage index* is taken from the CMS provider wage index file or impact file. If not found, take wage index from CBSA wage index file or inpatient provider specific file;
- The *covered length of stay* is calculated as the maximum of utilization days and cost report days. If either is 0, take the discharge date minus admission date plus one as the covered days.

2. New Technology Add-On Payments

- Check the applicable relevant Diagnosis, Procedure, and Drug code on the claim to determine if the claim is eligible to receive new-tech add-on payment.
- Calculate the new-tech payment as the maximum amount for the new-tech or the operating loss multiplied by the new-tech factor, whichever is smaller.
- The operating loss is defined as operation cost minus operating DRG

[319] PPS payment is made at the stay level instead of the claim level, that is, there will be up to one final claim per inpatient stay. CAHs can split-bill an inpatient stay, that is, multiple claims that make up one stay can have positive payment. In order to calculate PPS payment for CAH claims, stay grouping is necessary.

[320] This value is set by statute and is the same value every year.

payment (defined in the ''DRG Payment'' section above).

• Perform New-Tech add-on calculation for all applicable new technologies found on claim and sum all eligible New-Tech add-ons as total new-tech add-on.

3. Outlier Payments

• Calculate outlier payment as the excess cost over outlier threshold multiplied by the cost sharing factor. Cost is defined as the sum of operating cost and capital cost;

• *Operating cost* is estimated by total covered charges multiplied by operating cost-to-charge ratio;

• *Capital cost* is estimated by total covered charges multiplied by capital cost-to-charge ratio, divided by wage index of provider raised to the power of 0.6848.

4. Clotting Factor Payments

• Calculate the clotting factor payment as the multiplication of revenue unit of clotting factor line and the clotting factor payment rate from the Part B drug ASP file.

5. Adjusting PPS Payment

The following sections describe adjustments to the payment calculation. This methodology includes Disproportionate Share Hospital (DSH) payment, Uncompensated Care Payment (UCP), Indirect Medical Education (IME) payment, and Low-Volume Adjustment (LVA) payment. Performance-based payment adjustments, such as Value-based Purchasing, Hospital Readmission Reduction Program, and Hospital-Acquired Condition Reduction Program, are not included. These performance programs typically exclude CAHs and are of smaller magnitude than IME, DSH, UCP and LVA. As stated previously, there are no payment trends with the VBP, HRRP, and HAC reduction program in the rural IPPS hospital data, and we decided to not include these adjustments in the estimate of projected prospective payment for CAHs.

a. Disproportionate Share Hospital (DSH) and Uncompensated Care Payment (UCP)

The DSH payment adjustment and UCP are both provider-specific add-on payments for IPPS claims. In order to apply these two adjustments to CAHs, we must assess how they are calculated for IPPS hospitals. DSH is a percentage-based adjustment to the IPPS DRG payment that is determined by the sum of: (1) the percentage of Medicare inpatient days attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. UCP is determined by the percent of individuals under 65 who are uninsured, and hospitals' amounts of uncompensated care. These calculations are performed in addition to calculating the percentage of Medicare inpatient days attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but bot Medicare Part A. All of the factors used in determining DSH/UCP are ultimately determined by the demographics of the patient populations hospitals serve. Operationally, CMS collects and calculates these factors from hospitals' cost report data from prior years. If CAHs' cost report data were as complete and timely as that of IPPS hospitals, DSH and UCP could be calculated for CAHs in the same way. However, because CAHs are reimbursed based on reasonable cost, they do not have the same incentives to complete their cost reports as IPPS hospitals. Because of the data availability and validity concerns, we do not propose to calculate DSH/UCP directly from cost report data.

To simplify the calculations, define the DSH UCP ratio as the ratio of a hospital's total DSH and UCP payment amount over its core payment (*i.e.,* inpatient hospital DRG payment before the inclusion of supplemental payments) for 2019. The goal is to calculate a reasonable DSH UCP ratio for CAHs. Starting from the premise that DSH/UCP are determined by the demographics the hospitals serve, we take the following steps:

• Select IPPS hospitals that are located in rural areas.

• For each CAH, identify the IPPS hospital that is closest based on distance from the CAH.

• Identify the closest rural IPPS hospital and then calculate the average DSH UCP ratio for that hospital.

As a validation, we run a linear regression model that predicts an IPPS hospital's DSH UCP ratio using urban/rural indicator, the percentage of population below the poverty line (at zip code level, obtained from American Community Survey) and the percentage of dually enrolled inpatient beneficiaries (calculated from claims and enrollment data). Then, apply the parameter estimates of the model to the CAHs (*i.e.,* out of sample prediction) and calculate the average predicted DSH UCP ratio. The results show all the covariates are significant predictors of DSH UCP ratio. Furthermore, the validation produces very similar DSH UCP ratios for CAHs as the proposed method.

After we calculate and validate the DSH UCP ratios for the CAHs, we multiply the ratios by the core payment amount for each CAH to determine the estimate amount of DSH and UCP payments the CAH would receive. We then add the DSH and UCP payment amounts to the estimated prospective payment for the CAH.

b. Indirect Medical Education (IME)

The IME payment is a provider-specific add-on payment for IPPS claims. The IME adjustment factor is determined by a hospital's ratio of residents to beds. Operationally, CMS collects and calculates the adjustment from hospitals' cost report data from prior years. Because of the data availability and validity concerns (stated above), we do not propose to calculate IME payment directly from cost report data.

Instead, we propose to define the IME ratio as the ratio of a hospital's total IME payment over its core payment (*i.e.,* DRG payment) for 2019. The goal is to calculate a reasonable IME ratio for CAHs. We take the following steps:

• Select IPPS hospitals that are located in rural areas.

• For each CAH, identify the IPPS hospital that is closest to it.

• Identify the closest rural IPPS hospital and then calculate the IME ratio for the rural IPPS hospital for 2019.

As validation, run a linear regression model that predicts an IPPS hospital's IME ratio using urban/rural indicator and the average IPPS DRG weight per discharge (calculated from claims data). The urban/rural indicator is assumed to be correlated to the likelihood of a hospital to run an approved graduate medical education (GME) program and attractiveness of such program to medical school graduates; the average IPPS DRG weight is a measurement of level of complexity of inpatient care a hospital provides and is assumed to be correlated to the size of and need for GME. The results show both urban/rural indicator and average IPPS DRG weight per discharge are significant predictors of IME ratio.

c. Low Volume Adjustment

The Low-Volume Hospital Payment Adjustment is an additional payment adjustment based on the per discharge amount (including capital, DSH, IME, and outlier payments) to the qualifying IPPS hospitals during CY 2019. For discharges occurring in FYs 2019 through 2022, the qualifying criteria are:

(1) the hospital is more than 15 road miles from another subsection (d) hospital, and (2) the hospital has less than 3,800 total discharges during the fiscal year. If these qualifying criteria for the Low-Volume Hospital payment adjustment were also applied to CAHs, they meet the first criterion, as CAHs must be located either more than 35-miles from the nearest hospital or more than 15 miles in areas with mountainous terrain or with only secondary roads. We then check the number of total discharges from each CAH to determine if the CAH has less than 3,800 total discharges. The adjustment factor is calculated using the following formula for hospitals between 500 and 3,800 total discharges:

Low-Volume Hospital Payment Adjustment = 0.25 − [0.25/3300] × (number of total discharges − 500) = (95/330) − (number of total discharges/13,200)

If a hospital has less than 500 total discharges, then the low-volume hospital payment adjustment is 25 percent. The number of total discharges of CAHs is obtained from Hospital Cost Report Data, Worksheet S–3, Part I, Line 14, and Column 15.

6. Other Adjustments

- Device credit (if applicable) is deducted from the claims payment.
- Sequestration:

++ Subtract the actual coinsurance and deductible amount from PPS payment, and

++ Remove 2 percent as sequester reduction.

- Subtract the sequester reduction from the PPS payment.

Step 2: Proposed CAH Inpatient Rehabilitation Facility (IRF) and Inpatient Psychiatric Facility (IPF) PPS Payment Calculation

- IRF PPS rules that applied in FY 2019 or FY 2020 based on date of service to claims furnished by the rehabilitation units of CAHs.
- IPF PPS rules that applied in FY 2019 or FY 2020 based on date of service to claims furnished by the psychiatric units of CAHs.
- The Rehabilitation and Psychiatric Units of CAH are actually paid by IRF PPS and IPF PPS payment rules; therefore, we calculate their PPS payment by summing up their actual payment.

Step 3: Proposed Outpatient PPS Payment Calculation

Preparing Outpatient Claims for CAHs

Identify CAH outpatient hospital claims. Feed CAH claim lines to the IOCE grouper software to assign Status Indicator, Ambulatory Payment Classification (APC) code,[321] and Discount Formula Indicator.

Calculating OPPS Payment for CAHs

- Flag claim lines that have OPPS payable status indicator.[322] For claim lines that have APC assignment, obtain relevant APC payment rate from the OPPS Final Rule/Correction Notice data files. Apply the following APC adjustments, as applicable:

++ Device Credit, taken from value code ''FD'', is deducted from payment;

++ Off-campus Provider Based Department deduction indicated by modifier PO;

++ Computed tomography reduction (indicated by modifier CT and HCPCS code);

++ Reduction of X-rays taken with film (indicated by modifier FX);

++ 22.5 percent ASP rate reduction for Part B drugs (indicated by modifier JG and status indicator K).

- Adjust APC payment rate with OPPS discount factor based on the Discount Formula Indicator.
- Multiply adjusted APC payment rate with the number of revenue units to get APC payment.
- Adjust APC payment with geographic adjustment factor.

++ Geographic adjustment factor is the sum of labor share multiplied by wage index and non-labor share;

++ Wage index is determined by the wage index file, CBSA code, and provider specific record of the provider.

- Calculate line outlier payment by multiplying excess line cost over line multiple threshold with OPPS loss share ratio, if line estimated cost is greater than line multiple threshold and line fixed threshold.

++ Estimate claim line cost by adding line covered charge and charges from packaged services;

++ Line fixed threshold is the line OPPS payment plus the OPPS fix threshold of the calendar year

++ Line multiple threshold is line OPPS payment multiplied by the OPPS outlier factor of the calendar year

- Aggregate claim line level payment to claim level and apply sequester reduction to calculate final PPS payment for CAHs.

Calculating Payment for Other Claim Lines

Calculate payment for other claim lines with applicable fee schedule rules (OPPS Status Indicator ''A'').

- Clinical Lab Fee Schedule lines.
- Physician Fee Schedule lines.
- Ambulance Fee Schedule lines.
- Parenteral and Enteral Nutrition Fee Schedule lines.
- Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee (DMEPOS) Schedule lines.
- Vaccine and Part B drug lines.

(2) Detailed Proposed Methodology To Estimate CY 2019 Prospective Payment for CAHs for Provision of Skilled Nursing Facility Services

We also propose to use CAH claims to make estimates of the prospective payment amounts for skilled nursing swing bed payments. Under the SNF PPS, facilities are paid a pre-determined daily rate for each day of SNF care for each individual provided services, adjusted by each patient's unique medical needs and diagnoses. In order to calculate PPS payment for CAH claims that were not paid under PPS, we propose to assign a PPS equivalent daily rate to CAH claims factoring in patient case mix. CAH swing bed claims generally do not have minimum data set (MDS) records (that is, assessment data), which are the critical input to the Grouper software for Resource Utilization Group (RUG)/Patient Driven Payment Model (PDPM) code assignment. Therefore, RUG/PDPM codes for the CAH claims cannot be generated by the RUG/PDPM Grouper software. The RUG codes (which have been phased out of the SNF PPS, to be replaced by the PDPM) are determined mainly by the number of therapy minutes provided or expected to be provided to the beneficiary. However, the therapy minute variable is reported only through the MDS and not recorded on claims. Because of the lack of MDS data, RUG/PDPM rates cannot be directly obtained from the CAH swing bed claims. However, RUG/PDPM rates of CAH swing-bed claims can be predicted by modeling the RUG/PDPM per-diem-rates of claims that were actually paid under PPS rules. Under the statute, the SNF benefit must generally be qualified by a preceding inpatient stay. The information on the qualifying inpatient claim can be used to predict the RUG/PDPM per-diem-rate.

On October 1, 2019, a new case-mix classification model, the PDPM, under SNF PPS began. The use of RUG coding assignments ended, and the use of PDPM coding assignments started. We

[321] Since CAH outpatient claims have type of bill ''85x'', the IOCE software will not assign status indicator or APC code. In order to use the software properly, change the type of bill to ''131'' (the same bill type OPPS hospitals use to bill) before feeding the claims to the software.

[322] First digit of status indicator to be ''F'', ''G'', ''H'', ''J'', ''K'', ''L'', ''P'', ''Q'', ''R'', ''S'', ''T'', ''U'', ''V'', and ''X''.

propose to apply RUG PPS rules for claims with service dates between January 1, 2019, and September 30, 2019, and we propose to apply PDPM rules for those with service dates between October 1, 2019, and December 31, 2019. The primary steps to estimate the projected prospective skilled nursing payment for CAHs are as follows:

Step 1: Use the PPS payment calculation formula to estimate payment for skilled nursing facility PPS claims.

Step 2: Process claims using the RUG/PDPM rate prediction model.

Step 3: Use the PPS payment calculation formula to estimate payment for CAH swing-bed claims.

For more detailed information regarding the methodology for each of the steps listed to estimate the aggregate projected prospective payment for CAH skilled nursing services, please refer to the supplementary document ''Calculation of Rural Emergency Hospital (REH) Monthly Additional Facility Payment for 2023'' on the CMS website.

d. Proposal To Determine the Total Number of CAHs in CY 2019

We propose to use the CAH claims data to determine the total number of CAHs in CY 2019, which is required to determine the amount of the monthly facility payment pursuant to section 1834(x)(2)(C)(ii) of the Act. We propose that the number of CAHs in 2019 should be calculated as the distinct count of CAH CMS certification numbers (CCNs) that have any paid Medicare FFS claims from January 1, 2019 to December 31, 2019, based on service date. We propose that the number of distinct CAH CCNs includes providers that may have either been open or closed during CY 2019. We propose that CAHs that were open for only part of the year in CY 2019 will be reported as full providers in our count of distinct CAHs and will not be weighted in the count by the portion of the year they were open. Section 1834(x)(2)(C)(ii) of the Act requires that we use the number of CAHs that were in existence during 2019 and does not make any provision for counting CAHs only open for a part of the year differently from CAHs open the entire year. We propose to check the CCNs to ensure that if a CAH reports claims data from rehabilitation, psychiatric, skilled nursing facility or swing bed units in addition to the primary hospital unit, that only one facility is included in the count of total CAHs. We propose to codify our methodology to calculate the number of CAHs in CY 2019 under 42 CFR 419.92(b)(1)(iii).

e. Proposed Calculation of the Monthly REH Facility Payment for CY 2023

As stated above, section 1834(x)(2) of the Act requires an additional facility payment be paid monthly to an REH. For CY 2023, we propose that this facility payment be determined, per the requirements of the CAA and consistent with our proposed regulation text at 42 CFR 419.92(b)(1), using the following calculation:

Step 1: The total amount of Medicare spending for CAHs in CY 2019 (as described in section 1834(x)(2)(C)(i)(I) of the Act) minus the projected Medicare spending for CAHs in CY 2019 if inpatient hospital services, outpatient hospital services, and skilled nursing services had been paid on a prospective basis rather than at 101 percent of total cost (as described in section 1834(x)(2)(C)(i)(II) of the Act) and calculated according to the methodology described above.

Total Amount of Medicare Spending for CAHs in CY 2019: $12.08 billion

Total Projected Amount of Medicare Spending for CAHs if Paid Prospectively in CY 2019: $7.68 billion

Step1 Difference: $12.08 billion − $7.68 billion = $4.40 billion

Step 2: The difference in Step 1 would be divided by the number of CAHs enrolled in Medicare in CY 2019 to calculate the annual payment per individual REH. The annual payment amount would be divided by 12 to calculate the monthly REH facility payment. Each REH would receive the same facility payment.

Step 1 Difference: $ 4,404,308,465

Number of Medicare CAHs in CY 2019: 1,368

REH Monthly Facility Payment: ($4,404,308,465/1,368)/12 = $268,294

Using this calculation, we propose that the monthly facility payment for REHs for CY 2023 would be $268,294. We are seeking public comments on our methodology to determine the total amount was paid by Medicare to all critical access hospitals in 2019, our methodology to estimate the total amount that would have been paid to CAHs in 2019 for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems, and our overall methodology to calculate the monthly REH facility payment for CY 2023.

f. Proposed Calculation of the Monthly REH Facility Payment for CY 2024 and Subsequent Calendar Years

Section 1834(x)(2)(B) of the Act states that ''[t]he annual additional facility payment amount specified in this subparagraph is . . . for 2024 and each subsequent year, the amount determined under this subparagraph for the preceding year, increased by the hospital market basket percentage increase.'' Accordingly, we are proposing to codify, at 42 CFR 419.92(b)(2), that for CY 2024 and each subsequent calendar year, the amount of the additional annual facility payment is the amount of the preceding year's additional annual facility payment, increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

6. Preclusion of Administrative or Judicial Review

Section 1861(kkk)(9) of the Act explicitly precludes administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of (1) the establishment of requirements by the Secretary under subsection 1861(kkk) of the Act; (2) the determination of payment amounts under section 1834(x) of the Act, including the determination of additional facility payments; and (3) the determination of whether a rural emergency hospital meets the requirements of subsection 1861(kkk) of the Act.

Consequently, we propose to codify, at § 419.94, the preclusion of administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of (1) the requirements established by proposed Subpart K; (2) the determination of payment amounts under proposed Subpart K; and (3) the determination of whether an REH meets the requirements of proposed Subpart K.

7. Conforming Revisions to 42 CFR 410 and 413

In addition to codifying the requirements of section 1861(kkk) and 1834(x) of the Act at 42 CFR 419 as proposed above, we propose to make conforming changes to 42 CFR 410, which describes the origin and destination requirements for the coverage of ambulance services, and 42 CFR 413, which specifies principles of reasonable cost reimbursement.

a. Rural Emergency Hospitals Ambulance Services Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use

of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggests that the Congress intended:

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility. Since April 1, 2002, payment for ambulance services is made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act.

We have established regulations at § 410.40 that govern Medicare coverage of ambulance services. Under § 410.40(e)(1), Medicare Part B covers ground (land and water) and air ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary. The origin and destination requirements for coverage of ambulance services are addressed in our regulations at § 410.40(f).

b. Proposed Revision to the Origin and Destination Requirements Under the AFS (42 CFR 410.40(f))

Section 125 of the Consolidated Appropriations Act, 2021, added section 1834(x)(3) of the Act for payment for ambulance services. Specifically, newly added section 1834(x)(3) of the Act states: ''For provisions relating to payment for ambulance services furnished by an entity owned and operated by a rural emergency hospital, see section 1834(l) of the Act.'' Accordingly, the statute makes clear that the ambulance provisions under section 1834(l) of the Act apply to REHs that owns and operates an ambulance transportation in the same manner that they do for other ambulance providers and suppliers that receive AFS payment for ambulance services. The previous section includes a discussion about this provision, including CMS's proposal, consistent with section 1834(x)(3) of the Act, to codify, at 42 CFR 419.92(c)(1), that an entity that is owned and operated by an REH that provides ambulance services will receive payment for such services under the ambulance fee schedule as described in section 1834(l) of the Act.

The REH is an appropriate destination for an ambulance transport if furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary. We propose to revise our regulations at § 410.40(f) to include REH as a covered origin and destination for ambulance transport.

There are several different types of ambulance providers and suppliers that are enrolled in Medicare and furnished ambulance services payable under the AFS, such as a hospital provider. We propose that an REH that owns and operates an ambulance transportation may enroll in Medicare as an ambulance provider and receive payment under the AFS if all coverage and payment requirements are met.

We invite comments on our proposals to include REHs as a covered origin and destination for ambulance transport under the AFS and that an REH that owns and operates an ambulance transportation may enroll in Medicare as an ambulance provider and receive payment under the AFS if all coverage and payment requirements are met.

c. Conforming Revisions to 42 CFR 413.1; 413.13 and 413.24

We also propose to make conforming changes to the regulation text specifying principles of reasonable cost reimbursement in 42 CFR 413 to incorporate references to REHs. Specifically, we propose to modify § 413.1(a)(1)(ii) by adding subparagraph (L), to state that Section 1834(x) of the Act authorizes payment for services furnished by REHs and establishes the payment methodology. We also propose to modify § 413.1(a)(2)(i) to add REHs to the listing of provider types covered by the regulations in 42 CFR part 413. Additionally, we propose to amend § 413.13(c)(2) by adding subparagraph (vii) to the listing of services not subject to the lesser of costs or charges principle, to specify that services furnished by REHs are subject to the payment methodology set forth in part 419, subpart K.

Furthermore, we propose to amend § 413.24(f)(4)(i) to specify that an REH is required to file annual cost reports, and to amend § 413.24(f)(4)(ii) to specify that effective for cost reporting periods beginning on or after January 1, 2023, REHs are required to submit their cost reports in a standardized electronic format. Finally, we propose to amend § 413.24(f)(4)(iv)(A), which requires providers to submit a hard copy of a settlement summary, if applicable, and the certification statement described in § 413.24(f)(4)(iv)(B), by adding subparagraph (5) to state that for REHs, these requirements are effective for cost reporting periods beginning on or after January 1, 2023.

B. REH Conditions of Participation

Section 125 of Division CC of the Consolidated Appropriations Act, 2021 (CAA) added a new section 1861(kkk) to establish REHs as a new Medicare provider type to address the growing concern over closures of rural hospitals. The CAA created a pathway for certain critical access hospitals (CAHs) and certain rural hospitals to convert to this new provider type, allowing for continued access to emergency care in rural areas. In accordance with the statute, a facility is eligible to be an REH if it was a CAH or rural hospital with less than 50 beds as of the date of enactment of the CAA (December 27, 2020). REHs must provide emergency services and observation care and they may not provide inpatient services. Additionally, REHs may provide skilled nursing facility services in a separately certified distinct part skilled nursing facility. The statute also allows the Secretary discretion to establish additional requirements for REHs in the interest of health and safety.

CMS published a Request for Information (RFI) for REHs in the CY 2022 OPPS/ASC proposed rule on August 4, 2021, and used this information to inform our development of the REH health and safety, payment, quality measures, and enrollment policies. The proposed health and safety standards (that is, the Conditions of Participation) for REHs were published in the **Federal Register** on July 6, 2022 titled ''Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital CoP Updates'' (87 FR 40350), while the proposed payment, quality measures, and enrollment policies are included in this proposed rule. All of the final health and safety, payment, quality measures, and enrollment policies will

be published in the CY 2023 OPPS/ASC final rule with comment period.

C. REH Provider Enrollment

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overall purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. Since 2006, we have taken steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges. All enrolling and enrolled Medicare providers and suppliers, irrespective of type and including REHs, must comply with these regulatory provisions.

Section 1861(kkk)(2)(A) states that REHs must be enrolled under section 1866(j) of the Act. We are proposing several provisions that identify the enrollment requirements with which REHs must comply as part of the enrollment process.

1. General Compliance With Part 424, Subpart P

In addition to the previously mentioned requirement for REHs to enroll in Medicare, section 1861(kkk)(4)(B) of the Act states that an REH's enrollment remains in effect until: (1) the REH elects to convert back to its prior designation as a CAH or a hospital (as defined in section 1886(d)(1)(B) of the Act); or (2) the Secretary determines that the facility does not meet the requirements for REHs under this subsection. We are concerned that section 1861(kkk)(4)(B) of the Act could be misconstrued to suggest that our ordinary enrollment authorities do not apply to REHs (such as the authority to revoke the REH's enrollment if, for example, the provider: (1) certifies as ''true'' misleading or false information on the enrollment application; (2) abuses its billing privileges; or (3) fails to report certain required information). To clarify and confirm that our enrollment authority under subpart P applies to REHs to the same extent it does to all other Medicare provider and supplier types, we propose to add a new § 424.575 to subpart P. Paragraph (a) of this section would state that an REH (as that term is defined in 42 CFR 485.502) must comply with all applicable provisions and requirements in this subpart in order to enroll and maintain enrollment in Medicare.[323] We note that these requirements would include, but not be limited to, the following:

- Per § 424.510(a)(1) and (d)(1), completion and submission of the applicable enrollment application, which, for REHs, would be the Form CMS–855A (Medicare Enrollment Application: Institutional Providers; OMB control number 0938–0685).
- Submission of all required supporting documentation with the enrollment application per § 424.510(d)(1) and (d)(2)(iii).
- Per § 424.510(d)(5), completion of any applicable State surveys, certifications, and provider agreements.
- Reporting changes to any of the REH's enrollment information per § 424.516.
- Revalidation of enrollment per § 424.515.
- Undergoing risk-based screening per § 424.518 (discussed further in section XVIII.C.2 of this proposed rule).

Another requirement in subpart P pertains to application fees. Section 424.514 states that institutional providers submitting an initial or revalidation application, or adding a new practice location, must submit either or both of the following: (1) the applicable application fee (which, for CY 2022, is $631); or (2) a request for a hardship exception to the application fee. The term ''institutional provider'' is defined (for purposes of the application fee) in § 424.502. It means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and non-physician practitioner organizations) (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB control number 0938–1377), Form CMS–855S (Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB control number: 0938–1056), or an associated internet-based PECOS enrollment application.

Although an REH would submit a Form CMS–855A to enroll as such, it would not have to pay an application fee with its application. This is because we are proposing at new § 424.575(b) that the REH would submit a Form CMS–855A change of information under § 424.516 instead of an initial enrollment; that is, the facility would be merely reporting its conversion from a CAH or a hospital (as defined in section 1886(d)(1)(B) of the Act) to an REH—as well as submitting any other required information and documentation—and not newly enrolling in the Medicare program. Since this particular REH enrollment transaction would not be an initial enrollment, revalidation, or practice location addition, the fee payment requirement in § 424.514 would be inapplicable.

Our general policy has long been that a provider or supplier that is changing its provider or supplier type (for example, a home health agency switching to a home infusion therapy supplier) must terminate its existing enrollment and initially enroll as the new provider or supplier type. We believe the situation involving REHs is unique and warrants a deviation from this policy. Section 1861(kkk)(3) of the Act defines an REH, in part, as a facility that, as of the date of enactment of the Consolidated Appropriations Act, 2021 (December 27, 2020), was a CAH or a hospital (as defined in section 1886(d)(1)(B) of the Act). In addition: (1) section 1861(kkk)(4)(B)(i) of the Act references a ''conversion'' from an REH back to a CAH or a section 1886(d)(1)(B) hospital (rather than termination as an REH and initial enrollment as a CAH or section 1886(d)(1)(B) hospital); and (2) payments to REHs are to begin effective January 1, 2023, as already explained in this proposed rule. In light of this, and strictly from an enrollment application processing perspective, we believe there is a sufficiently close nexus between REHs and CAHs/section 1886(d)(1)(B) hospitals such that any conversion to an REH can be accomplished via a change of information application. We prefer this mechanism because such applications generally involve the mere disclosure of enrollment data that has changed as opposed to, with initial enrollments, the completion of the entire application. MACs can typically process change of information applications faster than initial applications. This is an important consideration given the need for CMS to also determine the facility's compliance with the REH conditions of participation before the REH can be enrolled as such. We want to ensure that the foregoing processes can be completed by January 1, 2023 so that

[323] This definition of rural emergency hospital is being proposed in the CMS proposed rule titled ''Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates.''

REHs can begin billing for services effective upon that date, and we believe permitting a change of information submission can help facilitate this. We note, however, that this deviation based on the unique circumstances of REH enrollment does not change our aforementioned general policy that requires an initial enrollment application for enrolled individuals and entities aiming to change their provider or supplier type.

2. Screening Risk Levels

Section 424.518 outlines provider enrollment screening categories and requirements based on our assessment of the risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the degree of scrutiny with which we will screen and review enrollment applications submitted by providers or suppliers within that category. There are three levels of screening addressed in § 424.518: limited; moderate; and high. Irrespective of which level a provider or supplier type falls within, the MAC performs certain minimum screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location. These include:

- Verification that the provider or supplier meets all applicable Federal regulations and State requirements for their provider or supplier type.
- State license verifications.
- Database reviews on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Moreover, for those in the high categorical risk level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's (FBI) Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are intended to correspond to the heightened risk involved with such provider or supplier types.

Hospitals currently fall within the limited screening category per § 424.518(a)(1)(viii). This also includes, as stated in § 424.518(a)(1)(viii), CAHs, Department of Veterans Affairs, and other federally-owned hospital facilities. We have no evidence to suggest that REHs as a category of provider type would present a risk of fraud, waste, and abuse warranting placement in the moderate or high screening level. Accordingly, we propose to revise § 424.518(a)(1)(viii) to incorporate REHs therein.

3. Effective Date of Billing Privileges

Section 424.520 lists the effective dates of billing privileges for enrolling Medicare providers and suppliers. For surveyed, certified, or accredited providers and suppliers, § 424.520(a) states that the effective date of billing privileges is that specified in 42 CFR 489.13. Paragraph (b) of the latter section states, in part, that the provider agreement or approval is effective on the date the State agency, CMS, or the CMS contractor survey is completed (or on the effective date of the accreditation decision, as applicable) if, on that date, the provider or supplier meets all applicable Federal requirements. Among these Federal requirements are the previously referenced enrollment requirements in Part 424, subpart P; as mentioned in 42 CFR 489.13(b), CMS determines the date on which all enrollment requirements have been met.

Hospitals and CAHs are among the provider types that fall within the scope of § 424.520(a). Since REHs, like other hospitals, would also come within the purview of § 424.520(a), it is unnecessary to revise § 424.520(a) to specifically reference them. We are merely discussing this issue in this proposed rule so that prospective REHs will understand what their effective date of billing privileges would be.

D. Use of the Medicare Outpatient Observation Notice by REHs

REHs are prohibited by section 1866(kkk)(2)(B) of the Act from providing inpatient services, other than those that are provided in a distinct part SNF. Section 2 of the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) (Pub. L. 114–42), amended section 1866(a)(1) of the Act by adding a new subparagraph (Y) that requires hospitals and CAHs to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours. The notification must explain the status of the individual as an outpatient, not an inpatient, and the implications of such status. We implemented section 1866(a)(1)(Y), as added by section 2 of the Notice Act, in the FY 2017 IPPS/LTCH final rule (81 FR 57037 through 57052).

REHs will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. There may be instances in which REH patients receive observation services at an REH for a period exceeding 24 hours, but REHs are not required to provide required notification under the NOTICE Act, known as the Medicare Outpatient Observation Notice (MOON), because REHs are excluded from the definition of ''hospital'' in section 1861(e) and the requirements at section 1866(a)(1)(Y) of the Act apply only to hospitals and CAHs. We understand that there may be occasional circumstances in which a facility is not immediately available to provide a higher level of care, resulting in patients receiving services at an REH for more than 24 hours. Notwithstanding the inapplicability of the NOTICE Act requirements at section 1866(a)(1)(Y) to REHs and the expected infrequency of individuals receiving observation services in REHs for more than 24 hours, CMS is soliciting comments on the potential need for REHs to notify beneficiaries of their status as outpatients, the implications of such status, and whether the MOON would be the appropriate notice for communicating this information.

E. Physician Self-Referral Law Update

1. Background

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose

a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. (For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.)

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule) and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was a final rule with comment period published in the January 4, 2001 **Federal Register** (66 FR 856). The second final rulemaking (Phase II) was an interim final rule with comment period (69 FR 16054) published in the March 26, 2004 **Federal Register**. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published in the April 6, 2004 **Federal Register** (69 FR 17933). The third final rulemaking (Phase III) was a final rule published in the September 5, 2007 **Federal Register** (72 FR 51012).

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the CY 2011 PFS final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 OPPS final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions to the physician self-referral law, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. In the December 2, 2020 **Federal Register**, we published a final rule entitled ''Modernizing and Clarifying the Physician Self-Referral Regulations'' (the ''MCR final rule'') (85 FR 77492) that established three new exceptions to the physician self-referral law applicable to compensation arrangements that qualify as ''value-based arrangements,'' established exceptions for limited remuneration to a physician and the donation of cybersecurity technology and services, and revised or clarified several existing exceptions. The MCR final rule also provided guidance and updated or established regulations related to the fundamental terminology used in many provisions of the physician self-referral law. Most notably, we defined the term ''commercially reasonable'' in regulation, established an objective test for evaluating whether compensation varies with the volume or value of referrals or other business generated between the parties, and revised the definitions of ''fair market value'' and ''general market value.'' The MCR final rule also revised the definition of ''indirect compensation arrangement,'' which was further revised in the CY 2022 PFS final rule (86 FR 65343 through 65353).

2. Application of The Physician Self-Referral Law To Rural Emergency Hospitals

The referral and billing prohibitions of the physician self-referral law are implicated only when all six of the following elements are present: a *physician* makes a *referral* for *designated health services* payable by *Medicare* to an *entity* with which the physician (or an immediate family member of the physician) has a *financial relationship.* Where all six elements exist, the physician self-referral law prohibits the physician from making a referral for designated health services to the entity with which he or she has the financial relationship unless an exception applies and its requirements are satisfied.

Our regulations at § 411.351 define ''entity'' to mean a person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes designated health services. Section 1877(h)(6) of the Act defines ''designated health services'' to mean any of the following items or services: clinical laboratory services; physical therapy services; occupational therapy services; outpatient speech-language pathology services; radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. Under the regulation at § 411.351, only services payable in whole or in part by Medicare are designated health services. Services that are paid by Medicare as part of a composite rate are excluded from the definition of ''designated health services.''

The proposals described in the proposed rule titled ''Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates'' (87 FR 40350), if finalized, would require an REH to furnish radiology and certain imaging services, clinical laboratory services, and outpatient prescription drugs, all of which are designated health services under section 1877(h) of the Act. An REH could elect to provide other designated health services as well. Therefore, with respect to such services furnished to Medicare beneficiaries, an REH would be an *entity* that furnishes *designated health services* payable (in whole or in part) by *Medicare* for purposes of the physician self-referral law.

For purposes of the physician self-referral law, a physician has the meaning set forth in section 1861(r) of the Act. A physician makes a referral when the physician requests or orders a designated health service, certifies or recertifies the need for a designated health service, or establishes a plan of care that includes the provision of a designated health service. (If the physician personally performs or provides the designated health service, the physician has not made a referral.) Under the regulations at § 411.354, a physician (or an immediate family member of a physician) has a financial relationship with an entity if the physician (or immediate family member) has a direct or indirect ownership or investment interest in the entity or has a direct or indirect

compensation arrangement with the entity.

Once an entity is enrolled in Medicare as an REH, the physician self-referral law would prohibit a *physician* from making a *referral* for designated health services to the REH if the physician (or an immediate family member of the physician) has a *financial relationship* with the REH unless an exception to the law's referral and billing prohibitions applies and all its requirements are satisfied. There are numerous statutory and regulatory exceptions to the physician self-referral law's prohibitions.

Although there are more than 40 exceptions to the physician self-referral law's prohibitions, only five permit all specified referrals by a physician to an entity in which the physician (or an immediate family member of the physician) has an ownership or investment interest when all requirements of the exception are satisfied. These are the exceptions for publicly traded securities, mutual funds, rural providers (commonly referred to as the ''rural provider exception''), hospitals in Puerto Rico, and hospitals outside of Puerto Rico (commonly referred to as the ''whole hospital exception''). Nine additional ''services'' exceptions in § 411.355, when applicable, may permit a physician's referral on a service-by-service basis, but the protection from the law's prohibitions requires an analysis of each referral by the physician and the resulting designated health service furnished by the entity.

We believe that most physician-owned entities that are not publicly traded or hospitals located in Puerto Rico rely on the rural provider and whole hospital exceptions in section 1877(d)(2) and (3) of the Act and in our regulations at § 411.356(c)(1) and (3), respectively. An entity that is a ''hospital'' for purposes of the physician self-referral law, including a critical access hospital or small rural hospital, may use either the rural provider exception (if applicable) or the whole hospital exception to avoid the law's referral and billing prohibitions, provided that all requirements of the selected exception are satisfied, including requirements set forth in the Affordable Care Act and included in our regulations at § 411.362.

The rural provider exception requires that the designated health services are furnished in a rural area and that the entity furnishes not less than 75 percent of the designated health services that it furnishes to residents of a rural area. For purposes of the physician self-referral law, a rural area is an area that is not an urban area, a term further defined elsewhere in CMS regulations to include certain areas defined by the Executive Office of Management and Budget (OMB). (See section XVIII.E.6 of this proposed rule for our proposal to make a technical amendment to the definition of ''rural area'' in § 411.351 to address changes in terminology used by OMB in its designation of these areas.) OMB regularly publishes updates to the list of areas that CMS considers to be urban areas. The whole hospital exception is available only to entities that are ''hospitals'' for purposes of the physician self-referral law. Under § 411.351, a hospital is an entity that qualifies as a ''hospital'' under section 1861(e) of the Act, as a ''psychiatric hospital'' under section 1861(f) of the Act, or as a ''critical access hospital'' under section 1861(mm)(1) of the Act.

Whether an entity furnishes designated health services in a rural area is subject to change as OMB updates the list of areas that CMS considers to be urban areas. Therefore, the continuous applicability of the rural provider exception to a particular entity is not guaranteed. Reliance on the rural provider exception also requires the entity to monitor the residence of the patients to whom it furnishes designated health services in order to ensure that the entity furnishes not less than 75 percent of the designated health services that it furnishes to residents of a rural area. As with the location where designated health services are furnished, whether an individual resides in a rural area is subject to change as OMB updates the list of areas that CMS considers to be urban areas, which may increase the monitoring burden.

Satisfaction of the requirements of the whole hospital exception is not dependent on whether the entity—which must be a hospital for purposes of the exception—furnishes designated health services in a rural area or where its patients reside. However, section 1861(e) of the Act, as amended by section 125 of the CAA, expressly excludes REHs from qualifying as a hospital for most Medicare purposes. Although critical access hospitals and small rural hospitals meet the definition of ''hospital'' in § 411.351, once a critical access hospital or small rural hospital converts to an REH, it will no longer be a ''hospital'' for purposes of the physician self-referral law and, therefore, the whole hospital exception will no longer be available to it. Although we considered deeming REHs to be hospitals for purposes of the physician self-referral law, which would have continued access to the whole hospital for such entities, as explained in section XVIII.E.4 of this proposed rule, we are not proposing to do so because we believe it would likely undermine the ability of REHs to ensure access to outpatient care for residents of rural and underserved communities as contemplated in the CAA.

We are concerned that, without a broadly-applicable exception to its referral and billing prohibitions for ownership or investment in REHs, the physician self-referral law could inhibit access to medically necessary designated health services furnished by REHs that are owned or invested in by physicians (or their immediate family members) and thwart the underlying goal of section 125 of the CAA to safeguard or expand such access. For this reason, using the Secretary's authority under section 1877(b)(4) of the Act to establish exceptions to the physician self-referral law for financial relationships that do not pose a risk or program or patient abuse, we propose a new exception at § 411.356(c)(4) for ownership or investment interests in an REH for purposes of the designated health services furnished by the REH. For purposes of this preamble, we refer to this exception as ''the proposed REH exception.''

We are not proposing any new exceptions for specific designated health services or for compensation arrangements between REHs and physicians (or immediate family members of physicians). We believe that, for the most part, the existing exceptions in §§ 411.355 and 411.357 are sufficiently comprehensive to allow for nonabusive referrals and compensation arrangements between REHs and physicians (or immediate family members of physicians). However, certain of the exceptions in § 411.357 are applicable only to compensation arrangements between a hospital (or other specific type of entity) and a physician (or an immediate family member of a physician). Because an REH is not considered a hospital for purposes of the physician self-referral law and is not one of the other specific types of entities to which the exceptions currently apply, for the reasons explained in section XVIII.E.5 of this proposed rule, and using the Secretary's authority under section 1877(b)(4) of the Act, we propose to amend our regulations to permit an REH to use these exceptions where doing so would not be a risk of program or patient abuse.

3. Proposed Exception for Rural Emergency Hospitals (Proposed § 411.356(c)(4))

a. Scope and Structure of the Proposed REH Exception

The proposed REH exception would be available only to entities that are ''rural emergency hospitals.'' To delineate the scope of the applicability of the proposed REH exception, we propose to amend § 411.351 to add a definition of ''rural emergency hospital'' for purposes of the physician self-referral law. Under proposed § 411.351, the term ''rural emergency hospital'' has the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91. As proposed, § 419.91 cross-references § 485.502, which is proposed in a separate rulemaking to define ''rural emergency hospital'' to mean an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. In addition, the entity must not provide inpatient services, except those in connection with a distinct part unit licensed as a skilled nursing facility to furnish post-hospital extended care services.

Section 1877(d) of the Act and § 411.356(c) establish exceptions for ownership of or investment in specific types of providers: rural providers, hospitals located in Puerto Rico, and hospitals located outside of Puerto Rico. These exceptions apply only with respect to referrals for and billing of the specific services identified in the relevant exception. For example, the exception at section 1877(d)(1) of the Act and § 411.356(c)(2) applies to all referrals and billing for designated health services furnished by a hospital located in Puerto Rico. In contrast, the exception at section 1877(d)(2) of the Act and § 411.356(c)(1) applies only to referrals and billing for designated health services that the entity furnishes in a rural area. The proposed REH exception follows the established construct of the existing exceptions for other specific providers and would apply to all referrals and billing for designated health services furnished by an REH. If all the requirements of the exception are satisfied, the referral and billing prohibitions of the physician self-referral law would not apply with respect to designated health services referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the REH.

Because all REHs would have been critical access hospitals or small rural hospitals prior to their enrollment in Medicare as an REH, we believe it is appropriate to include in the proposed REH exception program integrity requirements similar to those that apply to hospitals, including critical access hospitals and small rural hospitals, under the rural provider and whole hospital exceptions at § 411.356(c)(1) and (3)(iv). These requirements would apply to an REH even if it was not owned or invested in by physicians (or their immediate family members) when it was a critical access hospital or small rural hospital. We are not proposing to include every requirement of existing § 411.362 in the proposed REH exception; rather, our focus is on certain requirements in existing § 411.362(b)(4) that relate to ensuring *bona fide* investment as they would apply to an REH. In our view, requirements that relate to disclosure of conflicts of interest, prohibition on facility expansion, and prohibition on increasing aggregate physician ownership or investment levels are program integrity policies that the Congress applied specifically to physician-owned hospitals under the Affordable Care Act. If the Congress had intended all of these requirements to also apply to REHs, it could have considered an REH to be a hospital for purposes of section 1877 of the Act or expressly applied them to REHs under section 1877 of the Act. Importantly, we are concerned that limitations on facility expansion or the amount of physician investment or ownership in an REH could negatively impact access to needed services in rural and other underserved areas. Also, we are confident that the comprehensive set of program integrity requirements included in the proposed REH exception is sufficient to protect against program and patient abuse; therefore, the inclusion of other requirements in section 1877(i) of the Act and § 411.362, such as reporting and website disclosure requirements, is not necessary. We note that the requirement at existing § 411.362(b)(3)(ii)(B), which states that a hospital must not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital, is included under the statutory and regulatory set of requirements related to disclosure of conflict of interests. However, as explained in the Conference Committee report for the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), this requirement was seen as a requirement to ensure *bona fide* ownership and investment (Conference Committee report, H. Rept. No. 443, 111th Cong., 2nd Sess. 354 (2010)). We agree that it is a requirement to ensure *bona fide* ownership and investment and are proposing to include a similar requirement at proposed § 411.356(c)(4)(iii) as described later in this section XVIII.E.3 of this proposed rule.

We seek comment on this approach and whether we should apply more or fewer of the requirements related to physician-owned hospitals to physician ownership of or investment in an REH. We are considering whether to require that an REH must submit an annual report to CMS containing a detailed description of the identity of each owner of or investor in the REH, as well as the nature and extent of all ownership and investment interests in the REH. We would require that the REH submit the report at such time and in such manner as specified by CMS. In addition, we are seeking comment on whether we should require an REH to disclose on any public website for the REH and in public advertising for the REH that it is owned or invested in by physicians (or immediate family members of physicians), and require an REH to require that each physician with an ownership or investment interest in the REH who is a member of the REH's medical staff to agree, as a condition of continued medical staff membership, to provide written disclosure of their ownership or investment interest in the REH to all patients whom the physician refers to the REH. We would require that disclosure must be made by a time that permits the patient to make a meaningful decision regarding the receipt of care. We seek comment regarding the appropriateness of these requirements and whether they are necessary to protect against program and patient abuse.

b. Entity Enrolled as an REH

We propose that an entity that uses the proposed REH exception must be enrolled in Medicare as an REH. The requirement at proposed § 411.356(c)(4)(i) would ensure that a hospital (for purposes of the physician self-referral law) that may technically meet the definition of ''rural emergency hospital'' but is not enrolled in Medicare as such may not avail itself of the proposed REH exception. A hospital must instead use the rural provider or whole hospital exception, and all of the requirements in § 411.362 would apply, including the prohibitions on facility

expansion and exceeding the aggregate percentage of investment interests held by physicians (and their immediate family members) as of March 23, 2010. We seek comment on this proposed requirement.

c. Ownership in the Entire REH

We propose to require at proposed § 411.356(c)(4)(ii) that the physician's (or immediate family member's) ownership or investment interest is in the entire REH and not merely in a distinct part or department of the REH. This requirement is similar to the requirement at § 411.356(c)(3)(iii) in the whole hospital exception, and we would interpret it in the same manner for REHs. When the physician self-referral law was first enacted and later amended to apply to referrals of designated health services beyond clinical laboratory services, the Congress included the whole hospital exception to allow physician ownership or investment in hospitals because, at the time, there were a number of rural hospitals in particular where physicians held ownership interests, and avoiding barriers to accessible health care for patients in rural areas was imperative. These hospitals were usually the only hospitals in the area and provided a breadth of services, and therefore, the Congress did not view ownership or investment in the hospital as a significant incentive for self-referral. Even so, the whole hospital exception explicitly prohibited ownership in a subdivision of a hospital because of the concern that if physicians owned only the particular part of a hospital to which they referred—such as a cardiac wing or department—there would be an incentive for self-referral. (*See* Opening Statement of the Honorable Bill Thomas, Physician Ownership and Referral Arrangements and H.R. 345, ''The Comprehensive Physician Ownership and Referral Act of 1993,'' House of Representatives, Committee on Ways and Means, Subcommittee on Health, April 20, 1993, 145–146; Comments of the Honorable Pete Stark, Hearing before the Committee on Ways and Means of the U.S. House of Representatives 109th Cong., 1st Sess., 4–5 (Mar. 8, 2005) (Ser. No. 109–37); and House Committee on Budget Report on H.R. 3200 and H.R. 4872, H. Rep. No. 443, pt.1, 111th Cong., 2nd Sess., 355–356 (2010).) We similarly believe that ownership or investment in only a distinct part or department of an REH—such as an imaging center—would be an incentive for self-referral, and, therefore, that proposed § 411.356(c)(4)(ii) is necessary to protect against the harms the physician self-referral law was enacted to address, namely, overutilization and patient steering to less convenient, lower quality, or more expensive services and facilities. We seek comment on this proposed requirement.

d. Conditioning Ownership or Investment on Making or Influencing Referrals or Generating Business for the REH

In line with requirements for hospitals under the rural provider and whole hospital exceptions, we propose to require at § 411.356(c)(4)(iii) that the REH does not directly or indirectly condition any ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(3)(ii)(B), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way.

It is our position that an REH might fail to satisfy this proposed requirement if it requires a specified action or achievement with respect to referrals to or the generation of business for the REH prior to the purchase or receipt of the ownership or investment interest, or requires divestiture of an ownership or investment interest following the occurrence or nonoccurrence of a specified action or achievement with respect to referrals to or the generation of business for the REH. For example, we would consider an REH to condition the ownership or investment interest to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH if the physician was permitted to purchase an ownership interest in the REH only if the physician had ordered a specific number of advanced imaging services during each of the 2 years prior to the purchase date of the ownership interest. We would also consider an REH to condition an ownership or investment interest held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH if the REH required the physician to sell their ownership interest back to the REH in the event that they failed to perform a specific percentage of their outpatient surgeries at the REH during the current year or reduced the hours that they work in their private practice below 75 percent of the prior year. Similarly, the REH may not condition the amount of an ownership or investment interest that a physician (or an immediate family member of a physician) may purchase, receive, or maintain on the occurrence or nonoccurrence of a specified action or achievement under proposed § 411.356(c)(4)(iii). For example, if a physician who performs at least 80 percent of their surgeries at an REH would be permitted to purchase and maintain 20 shares in the REH, while a physician who performs only 25 percent of their surgeries at the REH would be permitted to purchase and maintain only 5 shares in the REH, we would consider the REH to condition an ownership or investment interest held or to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH. The examples provided here are for illustrative purposes only and are not intended to indicate, nor do they indicate, that any particular absolute number, percentage, or other standard is acceptable or unacceptable. We seek comment on our interpretation of what it means to ''condition'' an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH under proposed § 411.356(c)(4)(iii). We also seek comment specifically on whether we should consider an REH's policy or other mandate that a physician (or an immediate family member of a physician) must relinquish their ownership or investment interest in an REH upon the physician's full retirement from the practice of medicine or the relocation of the physician's medical practice to a location outside the REH's service area to fail to satisfy the proposed requirement at § 411.356(c)(4)(iii), as well as other examples of conduct that we should consider to ''condition'' an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH under proposed § 411.356(c)(4)(iii).

Like existing § 411.362(b)(3)(ii)(B), which applies to hospitals that use the rural provider and whole hospital exceptions, the requirement at proposed § 411.356(c)(4)(iii) prohibits policies and conduct that *directly or indirectly* condition ownership or investment interests held or to be held by a

physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. For purposes of this requirement, an REH *directly* conditions ownership or investment interests by adopting policies that require a specific number, volume, or value of referrals to or other business for the REH during a particular time period. For example, a requirement that a physician owner of an REH must have ordered at least 50 clinical laboratory tests during three of the prior four quarters to maintain their ownership (or level of ownership) would not satisfy the requirement at proposed § 411.356(c)(4)(iii). Similarly, a policy that permits an immediate family member to purchase an ownership or investment interest in an REH only if their child, who is a physician in private practice, increases the number of patients that they refer to the REH by 25 percent during the calendar year prior to the purchase would not satisfy the proposed requirement. However, if the REH directs the referrals of the physician under a *bona fide* employment relationship, personal service arrangement, or managed care contract between the REH and the physician, and the directed referral requirement meets all the conditions of § 411.354(d)(4), we would not consider the directed referral requirement to constitute directly or indirectly conditioning an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH.

For purposes of this requirement, we would consider an REH to *indirectly* condition ownership or investment interests if it adopted policies or standards of another person or organization to establish qualification criteria for purchasing or maintaining ownership or investment interests in the REH and those policies or standards required the physician to make or influence referrals to or generate business for the REH. For example, if an REH required that a physician have active medical staff privileges at the REH to hold an ownership or investment interest in the REH, and also approved the medical staff bylaws that required a minimum of 50 outpatient therapeutic services per year performed or supervised by the physician, the REH would likely not satisfy the requirement at proposed § 411.356(c)(4)(iii). This is because the REH would indirectly adopt the policy mandating a minimum of 50 outpatient therapeutic services per year as the REH's own criteria for qualification to hold an ownership or investment interest in the REH. We recognize that the medical staff of an entity, although accountable to the entity's governing body for the quality of patient care provided by medical staff members to the entity's patients, is independently organized under its own bylaws and establishes the criteria for appointment to the medical staff, credentialing, privileging, and oversight. We also recognize that an entity's medical staff is responsible for peer review, which, to be effective, requires the review of a minimum body of a medical staff member's work in order to determine whether to grant or continue active (or some other category of) medical staff privileges. We are not proposing, nor would we be able, to establish a bright-line rule applicable in all instances defining an acceptable number of referrals to or amount of business generated for an entity that a medical staff could require in order to complete effective peer review activities. Rather, such medical staff requirements must directly relate to its peer review obligations—including the evaluation of a physician's (or other practitioner's) individual character, competence, training, experience, and judgment—and not be a proxy for referrals to or the generation of business for the entity. To be clear, if an REH adopted a requirement that a physician owner of or investor in the REH must have active privileges at the REH, we would consider it to have effectively (albeit indirectly) adopted a condition that the physician owner must make the same number of referrals to or generate the same amount of business for the REH for purposes of the requirement at proposed § 411.356(c)(4)(iii) as the number of referrals to or amount of business for the REH that is required by the medical staff to hold active privileges at the REH. To illustrate, if the REH requires all physician owners or investors to maintain active medical staff privileges, and the REH's medical staff requires a physician to admit and treat a minimum of five patients per year to maintain active privileges, we would consider the REH to require a minimum of five admissions per year for physician owners to hold their ownership interests in the REH. Whether the requirement constitutes prohibited indirect conditioning of ownership or investment in the REH under proposed § 411.356(c)(4)(iii) requires a case-by-case determination, including a review of the underlying purpose of, need for, and available alternatives to the minimum requirement.

It is our position that there are many ways that an REH could indirectly condition an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. For example, an REH could require a physician to earn a minimum number of ''points'' in a year to maintain the physician's (or an immediate family member's) ownership interest or level of ownership. Although this would not *per se* be prohibited under proposed § 411.356(c)(4)(iii), if the required points are merely a proxy for referrals to or the generation of business for the REH (for example, if the physician is awarded one point for each designated health service that they order), we would consider the REH to indirectly condition an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. An REH could also indirectly condition ownership or investment interests under a points system if it awards points only for a physician's personally performed services but the personally performed services also result in the furnishing of designated health services by the REH. Whether a point system or other condition for ownership or investment in an REH runs afoul of proposed § 411.356(c)(4)(iii) requires a case-by-case determination. A point system that allows the awarding of only one point per patient closely ties the referral of the patient or the generation of the business to the physician who ordered the designated health service or other REH service and, therefore, would likely not be permissible. In contrast, a point system that awards points for a variety of physician activities, including activities that are not tied to the physician's own referral of the patient or business generated for the REH (such as points for chairing a committee of the REH, serving as an assistant at surgery, or providing a professional consultation for another physician's patient), may be permissible under proposed § 411.356(c)(4)(iii).

As we explained in the MCR final rule, our policies with respect to determining whether compensation is determined in any manner that takes into account the volume or value of a physician's referrals (the ''volume or

value standard'') or the other business generated by a physician (the ''other business generated standard'') have never applied and do not to apply for purposes of analyzing ownership or investment interests for compliance with the physician self-referral law, as none of our exceptions in § 411.356 include a requirement identical or analogous to the volume or value standard or other business generated standard (85 FR 77541). Any guidance regarding our interpretation of the volume or value standard or other business generated standard is not relevant for purposes of applying the exceptions at § 411.356(c)(1) and (3), both of which incorporate the requirements of § 411.362, including the requirement at § 411.362(b)(3)(ii)(B) that a hospital must not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital (85 FR 77541). The same is true with respect to the proposed REH exception—our interpretation of the volume or value standard and the other business generated standard is not relevant. Likewise, the interpretations with respect to the proposed REH exception explained in this proposed rule are not relevant for purposes of applying the special rules at § 411.354(d)(6) when analyzing compensation arrangements for compliance with the physician self-referral law.

Proposed § 411.356(c)(4)(iii) prohibits an REH conditioning any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician *making or influencing* referrals to the REH (or otherwise generating business for the REH). For purposes of the physician self-referral law generally, a physician makes a referral (as defined in § 411.351) by ordering the designated health service, writing a prescription for a designated health service, including the provision of a designated health service in a plan of care, certifying or recertifying the need for a designated health service, or otherwise requesting the designated health service. A physician also makes a referral when the physician requests a consultation with another physician and the consulting physician orders a designated health service to be performed by (or under the supervision of) the consulting physician. (A physician who transfers the care of a patient, in whole or in part, to another physician for specialty or other care to be provided by the other physician—as opposed to a request for a consultation with the other physician—does not make a referral for designated health services ordered or otherwise referred by the other physician.) A physician may make a referral orally, in writing, electronically, or in any other form. For purposes of proposed § 411.356(c)(4)(iii), we would interpret the making of referrals to an REH in the same way.

With respect to the influencing of referrals to an REH under proposed § 411.356(c)(4)(iii), impactful pressure or persuasion to refer, or an enforceable requirement for or control over the referrals of another, would demonstrate a physician's influence over the referrals of another physician to an REH. Under § 411.351, ''referral'' is defined in the context of a physician's action or conduct. We would interpret the term ''referral'' consistent with its meaning throughout the physician self-referral regulations, and interpret the requirement at proposed § 411.356(c)(4)(iii) to relate only to the influencing of referrals *by a physician* to the REH. For example, an REH would not satisfy the requirement at proposed § 411.356(c)(4)(iii) if it withheld the opportunity to purchase an ownership or investment interest in the REH from the physician owners of a physician practice unless the practice required all of its employed and contracted physicians to refer all of their patients to the REH for diagnostic testing and clinical laboratory services, or required them to perform all outpatient surgeries at the REH. (We note that, with respect to the employed and contracted physicians' referrals for designated health services furnished by the physician practice, the requirement for referrals to the REH may be permissible, provided that all requirements of § 411.354(d)(4) are satisfied.)

Proposed § 411.356(c)(4)(iii) also prohibits an REH conditioning any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician *otherwise generating business* for the REH. We would interpret the phrase ''otherwise generating business'' in proposed § 411.356(c)(4)(iii) consistent with our interpretation of the same and similar phrases in our other regulations. We addressed our interpretation of the phrase ''other business generated'' and its variations, such as ''otherwise generating business,'' in several of our prior rulemakings. We indicated that other business generated does not include a physician's personally performed services, but does include a referred technical component that corresponds to a physician's personally performed service (69 FR 16067 through 16068). We also indicated that other business generated by a physician includes Federal and private pay business (other than Medicare) (66 FR 877), as well as non-Federal health care business (69 FR 16068). It is important to highlight that these statements are examples of what is and is not ''other business generated'' for purposes of the physician self-referral law. Our longstanding interpretation of the phrase ''other business generated'' is that it means *any* other business or revenues generated by a physician (66 FR 877) (emphasis added). Although such business or revenues may be generated through the furnishing of health care services by the entity, our interpretation is not limited to business or revenue generated through the furnishing of health care services.

It is our position that a physician may generate business for an REH in a variety of ways, including, but not limited to, ordering services to be furnished or billed by the REH, writing a prescription for a service to be furnished or billed by the REH, establishing a plan of care for services to be furnished or billed by the REH, certifying or recertifying the need for services to be furnished or billed by the REH, or otherwise requesting services to be furnished or billed by the REH. A physician may also generate business for an REH that is unrelated to the REH's furnishing of health care services. We interpret the generation of business by a physician to include the physician's direct actions and the actions of others whom the physician directs or otherwise influences to generate business for the REH.

We seek comment on our interpretation of this proposed requirement and request specific examples of directly and indirectly conditioning any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. We are particularly interested in examples of conduct by an REH that would constitute ''conditioning'' of ownership or investment interests, as well as examples of conduct that we should not consider to condition ownership or investment interests. We are also interested in examples of conduct by a physician (or an immediate family member of a physician) that could ''influence'' referrals to an REH, as well as examples of conduct that we should

not consider to influence referrals to an REH.

e. Offer of Ownership or Investment on More Favorable Terms

We propose to require at § 411.356(c)(4)(iv) that the REH does not offer any ownership or investment interests to a physician (or an immediate family member of a physician) on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(ii), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way. For example, an REH that permits a physician owner or investor to pay for purchased shares in the REH over 5 years while requiring non-physicians to pay the full purchase price in advance of the purchase would not satisfy the proposed requirement. Similarly, an REH could not permit a physician to purchase additional shares in the REH every year while allowing non-physicians to purchase shares only once every 3 years.

We note that, in the requirement at existing § 411.362(b)(4)(ii) from which this proposed requirement is drawn, the word ''who'' follows ''person.'' We believe that the statutory requirement on which that regulation is based is intended to prohibit the offering of ownership or investment interests to physicians (or immediate family members of physicians) on terms more favorable than any other owner of or investor in a hospital. For this reason, we propose to use the word ''that'' following ''person'' to indicate that the person to which less favorable terms are offered could be a natural person (that is, an individual) or a non-natural person (that is, a corporation, partnership, or similar organization).

We seek comment regarding this proposed requirement and specific examples of conduct that would satisfy (or fail to satisfy) the proposed requirement.

f. Providing Loans or Financing for Ownership or Investment

We propose at § 411.356(c)(4)(v) to prohibit an REH and the owners of or investors in the REH from directly or indirectly providing loans or financing for any investment in the REH by a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(iii), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way. For purposes of this proposed requirement, an REH directly provides loans or financing by lending the funds or other assets of the REH for use in purchasing the physician's (or immediate family member's) ownership or investment interest in the REH. In such a case, the REH is the lender. Similarly, an individual or corporate owner of or investor in an REH directly provides loans or financing by lending their own funds or other assets for use in purchasing the physician's (or immediate family member's) ownership or investment interest in the REH.

An REH indirectly provides loans or financing for investment in the REH by controlling or meaningfully influencing another person's decision to lend funds or assets for use in purchasing the physician's (or immediate family member's) ownership or investment interest in the REH. In such a case, the REH is not the lender. For example, if an REH is the sole owner of the corporation that loans money to a physician to purchase an ownership or investment interest in the REH, we would consider the REH to indirectly provide the loan because the REH exercises control over its wholly-owned subsidiary corporation. In contrast, merely introducing a physician (or an immediate family member of a physician) to an individual or corporation that might lend funds or assets for use in purchasing an ownership or investment interest in an REH, in the absence of actual control or meaningful influence over the lender's decision whether a loan will be provided, would not constitute the indirect provision of a loan or financing for investment in the REH.

We seek comment on our interpretation of this proposed requirement and request specific examples of directly and indirectly providing loans or financing for investment in an REH.

g. Guarantee, Make a Payment on, or Otherwise Subsidize a Loan

At proposed § 411.356(c)(4)(vi), we propose to prohibit an REH and the owners of or investors in the REH from directly or indirectly guaranteeing a loan, making a payment toward a loan, or otherwise subsidizing a loan for a physician (or an immediate family member of a physician) that is related to acquiring any ownership or investment interest in the REH. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(iv), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way. We note that existing § 411.362(b)(4)(iv) extends the prohibition on guaranteeing, making a payment toward, or otherwise subsidizing a loan to such activities when they are for a group of physician owners or investors, whereas proposed § 411.356(c)(4)(vi) prohibits these activities as they relate to individual physicians (and immediate family members). A group of physician owners or investors is made up of individual physicians and, therefore, the proposed requirement would also prohibit guaranteeing, making a payment toward, or otherwise subsidizing a loan for a group of physician owners or investors.

For purposes of proposed § 411.356(c)(4)(vi), an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH guarantees a loan when the REH, owner, or investor formally or informally promises the lender that, should a physician (or an immediate family member of a physician) fail to make a required payment on a loan related to the physician's (or immediate family member's) acquisition of any ownership or investment interest in the REH, the REH, owner, or investor, respectively, will make or otherwise ensure that the payment will be made to the lender. A direct guarantee would include pledging the guarantor's own funds or assets as collateral for the guaranteed loan, whereas an indirect guarantee would include pledging or arranging for the pledge of the funds or assets of another individual or corporate entity as collateral for the guaranteed loan. We would also consider the pledge of funds or assets of an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH to guarantee a loan for property that serves as collateral for the loan related to acquiring the physician's (or immediate family member's) ownership or investment interest in the REH to be an indirect guarantee of such loan.

We would interpret the direct or indirect making of a payment toward a loan similarly. That is, a person directly makes a payment toward a loan by using the person's own funds or assets to make the payment, and indirectly makes a payment toward a loan by using or arranging for the use of the funds or assets of another individual or corporate entity to make the payment. An REH would not be prohibited from garnishing the wages or other

compensation due to a physician (or an immediate family member of a physician) to make loan payments on behalf of the physician (or immediate family member).

Finally, for purposes of proposed § 411.356(c)(4)(vi), an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH otherwise subsidizes a loan when the REH, owner, or investor pays part of the cost of a loan for a physician (or an immediate family member of a physician). Subsidies would include, for example, payments to reduce the principal amount of the loan, reduce the interest rate applied to the loan, or cover the cost of fees, such as origination fees, late fees, or early payoff penalties. As with guaranteeing or making payments toward a loan, we would interpret directly and indirectly subsidizing a loan to mean that a person directly subsidizes a loan by using the person's own funds or assets to pay part of the cost of the loan, and indirectly subsidizes a loan by using or arranging for the use of funds or assets of another individual or corporate entity to pay part of the cost of the loan.

We seek comment on our interpretation of this proposed requirement and request specific examples of direct and indirect guarantees of, payments toward, and otherwise subsidizing a loan for a physician (or an immediate family member of a physician) that is related to acquiring any ownership or investment interest in an REH.

h. Proportional Distributions

We propose to require at § 411.356(c)(4)(vii) that ownership or investment returns are distributed to each owner of or investor in an REH in an amount that is directly proportional to the ownership or investment interest in the REH of such owner or investor. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(v), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way. Simply put, distributions of profits, dividend payments, and other payouts on equity may only be tied to the number of shares owned by an investor, and not to their referrals or the other business the investor generates for the REH. We would interpret ''proportional'' as it is defined in the dictionary: corresponding in size or amount.

To ensure that the ownership or investment return to each owner of or investor in the REH is directly proportional to the particular owner's or investor's interest in the REH, all owners and investors must be treated the same. That is, if any owner or investor is eligible to receive or actually receives an ownership or investment return, all other owners or investors must be eligible to receive or actually receive an ownership or investment return, respectively. For example, an REH wholly-owned by physicians would not satisfy this proposed requirement if the REH made distributions only to physicians who generate a minimum amount of business for the REH during the ownership or investment period. In addition, an REH could not exclude owners or investors that are not physicians (or their immediate family members) from eligibility for ownership or investment returns for the purpose of making distributions only to owners or investors who are physicians in a position to generate business for the REH or their immediate family members. This would be the case even if the distributions were in amounts that are directly proportional to the physician's (or immediate family member's) ownership or investment interest in the REH.

We seek comment on our interpretation of this proposed requirement and request specific examples of potentially nonabusive classifications of owners or investors that could justify the distribution of ownership or investment returns only to a subset of owners or investors in an REH or in an amount that is not directly proportional to the ownership or investment interest in the REH of each owner or investor.

i. Guaranteed Receipt of or Right To Purchase Other Business Interests

We are also proposing to require that any physician (or immediate family member of a physician) who has an ownership or investment interest in an REH does not directly or indirectly receive any guaranteed receipt of or right to purchase other business interests related to the REH, including the purchase or lease of any property under the control of any other owner of or investor in the REH or located near the premises of the REH. This requirement is at proposed § 411.356(c)(4)(viii) and is essentially identical to the requirement at existing § 411.362(b)(4)(vi), which applies to hospitals that use the rural provider and whole hospital exceptions. We would interpret the requirements applicable to REHs and hospitals in the same way.

For purposes of this requirement, other business interests related to the REH would include a wide array of investment opportunities, ventures, and interests, as well as the examples of the purchase and lease of property under the control of any other owner of or investor in the REH that are listed in the statutory and regulatory requirements applicable to hospitals that use the rural provider and whole hospital exceptions. We would consider the business interests of any owner of or investor in the REH to be business interests related to the REH. For example, under the proposed requirement at § 411.356(c)(4)(viii), a physician owner of or investor in an REH may not directly or indirectly receive an interest in another component of the health care system that includes an REH upon the physician's purchase of their ownership or investment interest in the REH, nor may the physician owner directly or indirectly be guaranteed the right to invest in a venture in which another owner of the REH is also an investor. In these examples, the physician owner would directly receive an interest or be guaranteed the right to invest in a business interest related to an REH if the interest is held or would be held, if purchased, in the physician's name. In contrast, the physician owner would indirectly receive an interest or be guaranteed the right to invest in a business interest related to an REH if the interest is received by, held in the name of, or, if purchased, would be held in the name of a person or corporate entity over which the physician exercises meaningful control or influence, such as a partnership or limited liability company in which the physician holds a substantial interest. We seek comment on our interpretation of this proposed requirement and request specific examples of direct and indirect guaranteed receipt of other business interests, direct and indirect guaranteed rights to purchase business interests, and the types of business interests we should consider related to an REH.

j. Offer To Purchase or Lease Other Property on More Favorable Terms

Finally, at proposed § 411.356(c)(4)(ix), we propose to require that an REH does not offer a physician (or an immediate family member of a physician) the opportunity to purchase or lease any property under the control of the REH or any other owner of or investor in the REH on more favorable terms than the terms offered to a person that is not a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(vii), which applies to hospitals that use the rural provider and

whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way.

We highlight that there are two main differences between the requirements at proposed §§ 411.356(c)(4)(viii) and (ix). The former applies to any business interests related to the REH and prohibits the guaranteed receipt of or right to purchase such other business interests. The latter applies only to property under the control of the REH, an owner of the REH, or an investor in the REH, and prohibits the offering of the opportunity to purchase or lease such property on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician).

With respect to the prohibition on offering an opportunity to purchase or lease property on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician), we would interpret this requirement in the same way as proposed § 411.356(c)(4)(iv), which, as described earlier in this section XVIII.E.3 of this proposed rule, would prohibit an REH from offering any ownership or investment interests to a physician (or an immediate family member of a physician) on terms more favorable than those offered to a person that is not a physician (or an immediate family member of a physician). We note that the requirement at existing § 411.362(b)(4)(vii), from which this proposed requirement is drawn, states that the physician owner may not be offered the opportunity to purchase or lease certain property on more favorable terms than those offered to an ''individual'' who is not a physician owner or investor, in contrast to the requirement at existing § 411.362(b)(4)(ii), which references ''persons'' in a similar manner, as described earlier in this section XVIII.E.3 of this proposed rule. We believe that the statutory requirement on which existing § 411.362(b)(4)(vii) is based is intended to prohibit the offering of the opportunity to purchase or lease the specified property on terms more favorable than any other owner of or investor in a hospital. For this reason, proposed § 411.356(c)(4)(ix) includes the words ''person that'' in the same way as proposed § 411.356(c)(4)(iv) to indicate that the person to which less favorable terms are offered could be a natural person (that is, an individual) or a non-natural person (that is, a corporation, partnership, or similar organization).

4. Alternative To Proposed REH Exception Considered But Not Proposed

Section 1861(e) of the Act excludes critical access hospitals (formerly referred to as rural primary care hospitals) for most purposes of Title XVIII of the Act unless the context otherwise requires. However, as we explained in the 1998 proposed rule, we believe that the reference to context in this statutory provision indicates that critical access hospitals may be deemed to be hospitals where, in specific contexts, it is consistent with the purpose of the legislation to do so (63 FR 1681). For that reason, we included such entities in our definition of ''hospital'' at § 411.351 (66 FR 954). We based this policy on our belief that a physician who has a financial relationship with a critical access hospital is in as much of a position to profit from overutilizing referrals to the critical access hospital as they would be if the financial relationship was with an ordinary hospital. In addition, a critical access hospital provides services that are very similar to inpatient hospital services (63 FR 1681).

Section 125 of the CAA amended section 1861(e) of the Act to also exclude REHs from the definition of ''hospital'' for most Medicare purposes, unless the context otherwise requires. We considered whether to include REHs in the definition of ''hospital'' in § 411.351 for purposes of the physician self-referral law similar to our treatment of critical access hospitals. We are not proposing to do so for two primary reasons. First, REHs are not the same as critical access hospitals (or other hospitals that furnish inpatient care). By definition, an REH may not furnish inpatient care, a fundamental attribute of and requirement for a hospital for purposes of Medicare. (See section 1861(e) of the Act.) Second, if we were to consider an REH to be a hospital for purposes of the physician self-referral law, in order for an REH to avoid the law's referral and billing prohibitions, the ownership or investment interests of physicians (and their immediate family members) would have to satisfy the requirements of one of the existing exceptions applicable to such ownership or investment interests, which could prove challenging, thus limiting the ability of such potential investors to bring needed resources to underserved and rural communities. If we proposed to include REHs as ''hospitals'' for purposes of the physician self-referral law, we would not propose to establish the exception for ownership or investment in an REH with the requirements described in this section XVIII.E of this proposed rule because we do not believe that the Secretary's authority under section 1877(b)(4) of the Act would permit us to establish an exception that applies to only one type of hospital (for purposes of the physician self-referral law) without including the same (or equally stringent) program integrity requirements established by the Congress in statute.

To avoid the physician self-referral law's referral and billing prohibitions under the rural provider or whole hospital exception, an ownership or investment interest must satisfy the requirements of the applicable exception at the time of the physician's referral and the hospital must meet the requirements of section 1877(i) of the Act and § 411.362 no later than September 23, 2011. Section 1877(i)(1)(A) of the Act and § 411.362(b)(1) require that *the* hospital had physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act on that date (emphasis added). Put another way, for a hospital to bill Medicare (or another individual, entity, or third-party payer) for a designated health service furnished as a result of a physician owner's referral today, the hospital must have had both physician ownership or investment and a Medicare provider agreement on December 31, 2010. Thus, the hospital submitting the claim today must be the same hospital that had both physician ownership or investment and a Medicare provider agreement on December 31, 2010.

If we were to include REHs as hospitals for purposes of the physician self-referral law, certain REHs would be presumptively excluded from using the rural provider or whole hospital exceptions: REHs that had no physician owners or investors, as defined at § 411.362(a), on March 23, 2010 or December 31, 2010, and REHs that did not have a Medicare provider agreement in effect on December 31, 2010. Although we are uncertain how many REHs this would affect, we believe that prohibiting critical access hospitals and small rural hospitals that could not avail themselves of the rural provider or whole hospital exceptions prior to conversion to an REH from accepting investment in the REH by a physician (or an immediate family member of a physician) after conversion could undermine the purpose of section 125 of the CAA to safeguard access to necessary care for underserved patients and those in rural areas, and we are hesitant to do so.

Critical access hospitals and small rural hospitals that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 may avail themselves of the rural provider and whole hospital exceptions, provided that all other requirements of the applicable exception are satisfied. This would continue after conversion to an REH if we deemed REHs to be hospitals for purposes of the physician self-referral law. However, as noted above, the REH/hospital would have to be the same hospital that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 (the ''original hospital''). We would consider many factors when determining whether an REH would qualify as the same hospital that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 including, but not limited to: status of, type of, and party to the State license for both the REH and the original hospital, including any lapses in State licensure or operation of either the REH or the original hospital; status of and party to the Medicare provider agreement, including any lapses in Medicare participation of either the REH or the original hospital; whether the REH has the same Medicare provider number as the original hospital; the location and structure of the REH building(s) and those of the original hospital; whether the REH is under the same State's licensure regime as the original hospital; whether the REH serves the same community as the original hospital; whether the REH provides the same scope of services as the original hospital; REH ownership and that of the original hospital; and the number of operating rooms, procedure rooms, and beds operated by the REH and that of the original hospital. No one factor would be dispositive.

Finally, were we to deem REHs to be hospitals for purposes of the physician self-referral law, even those REHs that qualify to use the rural provider or whole hospital exception could not increase the amount of physician ownership or investment in the REH beyond the level of the original hospital on March 23, 2010. In addition, the REH could not expand its aggregate number of operating rooms and procedure rooms (it will likely not have licensed beds by definition) beyond the aggregate number of operating rooms, procedure rooms, and beds for which the original hospital was licensed on March 23, 2010 (or, in the case of an original hospital that did not have a Medicare provider agreement in effect as of March 23, 2010, but did have a Medicare provider agreement in effect on December 31, 2010, the effective date of its Medicare provider agreement) (its ''baseline number of operating rooms, procedure rooms, and beds''). Given that an REH may not furnish inpatient services under section 125 of the CAA and the regulations proposed in this proposed rule, the latter limitation may not have a significant impact on access to care in rural and other underserved areas, as an REH could continue to increase the number of its operating rooms and procedure rooms until it reached its baseline number of operating rooms, procedure rooms, and beds. However, as noted, we believe that physicians and their immediate family members may be an important source of needed capital for REHs. We are concerned that limiting the amount of physician ownership or investment in an REH to the level of such ownership or investment in the original hospital on March 23, 2010 could limit the services available to its patients and the community in which it is located and run counter to the purpose of section 125 of the CAA.

5. Applicability of Certain Exceptions in § 411.357 for Compensation Arrangements Involving REHs

Section 1877(e) of the Act and § 411.357 set forth exceptions to the physician self-referral law for compensation arrangements between entities and physicians (or immediate family members of physicians) when all requirements of the exception are satisfied. Some of these exceptions apply only to specified types of compensation, specified types of entities, or both. The exceptions in § 411.357 that are applicable only to compensation arrangements to which one party is a hospital, federally qualified health center, or rural health clinic would not be available to an REH because it is not a hospital under section 1861(e) of the Act or our regulations at § 411.351. We believe that many of these party-limited exceptions could be important to ensuring access to necessary designated health services and other care furnished by an REH. Therefore, using the Secretary's authority under section 1877(b)(4) of the Act, we propose to revise the exceptions at § 411.357(e), (r), (t), (v), (x), and (y) to make them applicable to compensation arrangements to which an REH is a party.

The current exceptions for physician recruitment (§ 411.357(e)), obstetrical malpractice insurance subsidies (§ 411.357(r)), retention payments in underserved areas (§ 411.357(t)), and assistance to compensate a nonphysician practitioner (§ 411.357(x)) are available to hospitals, federally qualified health centers, and rural health clinics. We propose to revise these exceptions to also permit an REH to provide remuneration to a physician if all requirements of the applicable exception are satisfied because we believe that REHs will face the same challenges as hospitals, federally qualified health centers, and rural health clinics in recruiting and retaining qualified physicians and other practitioners in their service areas. Consistent with our rationale when expanding the statutory exception for physician recruitment to federally qualified health centers (69 FR 16095), we propose the extension of these exceptions to REHs to help ensure that the physician self-referral law does not impede efforts by REHs, which will provide substantial services to underserved populations, to recruit, assist with the recruitment of, and retain adequate staffs. We do not believe that a compensation arrangement between an REH and a physician (or an immediate family member of a physician) that is properly structured to satisfy all the requirements of these exceptions would pose a risk of program or patient abuse. We are also proposing a technical amendment at proposed § 411.357(t)(5) to cross-reference the definition of the geographic area served by a federally qualified health center or rural health clinic that was previously omitted from this paragraph. The cross-referenced definition would also apply to REHs under this proposal.

The current exception for electronic prescribing items and services at § 411.357(v) is available only to hospitals, group practices that meet the requirements in § 411.352, PDP sponsors, and MA organizations and applies to hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information that is provided to physicians specified in the regulation. For the reasons set forth in this and many of our prior rulemakings regarding the benefits of electronic prescribing, we believe that allowing REHs to use the exception at § 411.357(v) would advance our goals to expand the use of electronic prescribing. We do not believe that a compensation arrangement between an REH and a

physician (or an immediate family member of a physician) that is properly structured to satisfy all the requirements of the exception would pose a risk of program or patient abuse.

The current exception for timeshare arrangements at § 411.357(y) is available only to hospitals and certain physician organizations (as defined in § 411.351) and applies to arrangements for the use of premises, equipment, personnel, items, supplies, and services. One of the underlying policy considerations for establishing this exception was to facilitate access to care in rural and other underserved areas (80 FR 71326). We believe that timeshare arrangements between REHs and physicians (or physician organizations in whose shoes such physicians stand under § 411.354(c)) may similarly increase access to necessary care for patients in underserved areas, and that it would be appropriate to extend the availability of the exception for timeshare arrangements to REHs. We do not believe that a compensation arrangement between an REH and a physician (or an immediate family member of a physician) that is properly structured to satisfy all the requirements of the exception would pose a risk of program or patient abuse.

We seek comment on our proposals to permit an REH to use the exceptions for physician recruitment (§ 411.357(e)), obstetrical malpractice insurance subsidies (§ 411.357(r)), retention payments in underserved areas (§ 411.357(t)), electronic prescribing items and services (§ 411.357(v)), assistance to compensate a nonphysician practitioner (§ 411.357(x)), and timeshare arrangements (§ 411.357(y)). Because the REH will not provide inpatient services and may elect not to provide outpatient services beyond emergency room and observation services, we are particularly interested in comments regarding the need for an REH to recruit physicians to establish or join medical practices in the geographic area served by the REH and how to define the geographic service area served by an REH for physician recruitment purposes. For the same reason, we are interested in comments regarding the need to extend the availability of the exception for assistance to compensate a nonphysician practitioners. We are also particularly interested in comments regarding the need for an REH to subsidize obstetrical malpractice insurance premium costs in light of the fact that an REH may elect not to serve obstetrical and newborn patients outside its emergency department.

We note that the current exception for medical staff incidental benefits at § 411.357(m) applies to items or services (not including cash or cash equivalents) provided to a member of the entity's medical staff. The exception applies to hospitals, as well as other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs. Prior to conversion to an REH, as a hospital for purposes of the physician self-referral law, a critical access hospital or small rural hospital would have been able to use the exception for medical staff incidental benefits. An REH that has a *bona fide* organized medical staff could use the exception for medical staff incidental benefits under current § 411.357(m)(8). However, we seek comment regarding whether we should revise § 411.357(m) to expressly include REHs as entities to which the exception applies.

6. Revised Cross-Reference in Definition of ''Rural Area'' for Purposes of the Physician Self-Referral Law

As discussed earlier in section XVIII.E of this proposed rule, the rural provider exception applies to designated health services furnished in a rural area. Section 1877(d)(2) of the Act defines ''rural area'' by reference to section 1886(d)(2)(D) of the Act. In the 1992 proposed rule, we proposed to define ''rural area'' as an area that is not an ''urban area,'' as the term is the term is defined at § 412.62(f)(1)(ii) (57 FR 8598). Section 411.62 established the Federal rates for inpatient operating costs for fiscal year 1984. We finalized the definition of ''rural area,'' including the reference § 412.62(f)(1)(ii), in the 1995 final rule (60 FR 41980). In the FY 2005 IPPS final rule, CMS revised the definitions of urban and rural areas based on OMB's revised standards for defining Metropolitan Statistical Areas (MSAs) (69 FR 49077). The revised definitions of urban and rural areas were codified at § 412.64(b). Section 412.64 establishes Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years. Despite the revised definition of rural and urban areas in the FY 2005 IPPS final rule, the definition of ''rural area'' as codified in § 411.351 for purposes of the physician self-referral law was never updated to reflect OMB's revised standards for defining MSAs. As a consequence, the current definition of ''rural area'' in § 411.351 includes, by reference to § 412.62(f)(1)(ii), terminology that is no longer employed by OMB, such as ''New England County Metropolitan Area (NECMA)'' (see, for example, 65 FR 51065). To ensure that the definition of ''rural area'' for purposes of the physician self-referral law is aligned with CMS' updated definitions of rural and urban areas at § 412.64 and takes into account OMB's revised standards for defining MSAs, we propose to modify the definition of ''rural area'' in § 411.351 to reference § 412.64(b) instead of § 412.62(f). Specifically, we propose to define ''rural area'' as an area that is not an urban area as defined at § 412.64(b) of this chapter. We believe that this technical change will have no effect on the entities that qualify as ''rural providers'' under § 411.356(c)(1). We seek comment on this proposal.

XIX. Request for Information on Use of CMS Data To Drive Competition in Healthcare Marketplaces

A. Background

On July 9, 2021, the President issued an Executive Order on Promoting Competition in the American Economy (E.O. 14036). According to E.O. 14036, ''robust competition is critical to preserving America's role as the world's leading economy,'' and ''the American promise of a broad and sustained prosperity depends on an open and competitive economy.''

A fact sheet released in conjunction with E.O. 14036 [324] goes on to identify hospital consolidation as a major concern, stating ''[h]ospital consolidation has left many areas, especially rural communities, without good options for convenient and affordable healthcare service.'' Research suggests that mergers in rural areas could result in reduced service lines and responsiveness to community needs.[325] Furthermore, in urban and rural areas, hospitals in consolidated markets charge far higher prices than hospitals in markets with several competitors. The Fact Sheet that accompanies E.O. 14036:

- Underscores that hospital mergers can be harmful to patients and encourages the Justice Department and the Federal Trade Commission to review and revise their merger guidelines to ensure patients are not harmed by such mergers.
- Directs HHS to support existing hospital price transparency rules and to finish implementing bipartisan Federal

[324] *https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/.*

[325] Hencke, RM, et al. ''Access To Obstetric, Behavioral Health, And Surgical Inpatient Services After Hospital Mergers In Rural Areas,'' *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.00160,* October 2021.

legislation to address surprise hospital billing.

Additionally, in 2018, MedPAC reviewed the literature and data on health care provider consolidation in response to a congressional request.[326] They found that by 2017, in most markets, a single hospital system had more than a 50 percent market share of discharges, and that hospital consolidation leads to higher prices for commercially insured patients. Furthermore, the literature synthesized by MedPAC suggested these high prices primarily reflected hospitals negotiating higher prices with insurers, rather than cost shifting as a result of lower Medicare or Medicaid rates. Even when Medicare or Medicaid revenues increase, hospitals still aimed to negotiate larger, rather than smaller, rate increases from commercial insurers. The MedPAC report concludes that ''taken together, these findings imply that hospitals seek higher prices from insurers and will get them when they have greater bargaining power.''

Research has similarly demonstrated that higher prices are also observed when physician practices merge, for example, one national study found that physicians in the most concentrated markets charged fees that were 14–30 percent higher than fees in the least concentrated markets.[327]

Overall, while provider mergers increased prices, their effects on quality were mixed. The MedPAC report noted ''Because the literature is mixed, we cannot make a definitive conclusion about the effect of mergers on the quality of care other than to say the effect is not large enough to result in consistent findings across studies.''

Over the years, CMS has undertaken several value-base purchasing activities that drive value care and support competition. For example, beginning in 2001, HHS and CMS began launching Quality Initiatives [328] to assure quality health care for all Americans through accountability and public disclosure. The various Quality Initiatives touch every aspect of the healthcare system. Some initiatives focus on publicly reporting quality measures for nursing homes, home health agencies, hospitals, and kidney dialysis facilities. Consumers can use the quality measures information that is available at *www.medicare.gov* for these healthcare settings to assist them in making healthcare choices or decisions. CMS also releases vast amounts of healthcare cost information that is available to the public, such as select measures provided by Medicare providers through their annual cost report,[329] and detailed use and payment information for procedures, services, and prescription drugs by specific inpatient and outpatient healthcare providers and suppliers.[330] CMS also finalized regulations designed to enhance healthcare price transparency to drive competition through its Hospital Price Transparency [331] and Transparency in Coverage [332] initiatives.

More recently, CMS has released data files to the public outlining hospital and nursing facilities' mergers, acquisitions, consolidations, and changes in ownership that were reported to the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) from 2016 to 2022, in order to promote transparency of these mergers, acquisitions, consolidations, and changes in ownership.[333]

PECOS is the System of Record for Medicare Provider Enrollment and was created to collect and maintain information regarding provider or supplier enrollment into Medicare. In addition to collecting information about individual practitioners or organizational entities, the CMS 855 forms collect information about ownership, authorized officials, delegated officials, managing employees, practice location, provider or supplier type, provider and supplier specific information, and affiliated provider information.

For additional information about the data that is collected in the PECOS system, please refer to the CMS 855 forms at this link: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Enrollment-Applications*.

In conjunction with this release of PECOS information showing hospital and skilled nursing facility mergers, acquisitions, consolidations, and changes in ownership, HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) also released a related report analyzing the CMS data to examine trends in changes of ownership over the 6 years.[334] The ASPE report identified several findings from the new data release including:

- Changes in ownership have been much more common in nursing homes than hospitals over the 6-year period.
- There is wide variation in ownership changes by State. For instance, 19 percent of hospitals (14 out of 73) in South Carolina were sold during the 6-year period, while most states had fewer than 4 percent of hospitals change ownership.
- A majority (62.3 percent) of skilled nursing facilities (SNFs) that were purchased have a single organizational owner, 6.9 percent have multiple organization owners, while 18.2 percent have only individual owners and 12.7 percent have both types of owners.

These merger, acquisition, consolidation, and changes in ownership data are available on *data.CMS.gov* and are expected to be updated on a quarterly basis going forward.

B. Request for Public Comment

In response to the E.O. 14036's call for a ''whole-of-government approach'' to address excessive concentration, abuses of market power, unfair competition, and the effects of monopoly and monopsony, CMS is seeking information from the public on how data that CMS collects could be used to promote competition across the health care system or protect the public from the harmful effects of consolidation within healthcare. Specifically, CMS seeks comment from the public on the following:

- What additional data that is already collected by form 855A (PECOS) would be helpful to release to the public and researchers, to help identify the impact of provider mergers, acquisitions, consolidations, and changes in ownership on the affordability and availability of medical care, and why?
- Do commenters suggest that CMS release data on any mergers, acquisitions, consolidations, and changes in ownership that have taken place for any additional types of providers beyond nursing facilities and hospitals? If so, for which types of providers?
- What additional information collected by CMS would be useful for the public or researchers who are studying the impacts of mergers,

[326] March 2018 Report to the Congress: Medicare Payment Policy. Accessed online 4/20/2022. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_entirereport_sec_rev_0518.pdf.*

[327] Abe Dunn and Adam Shapiro. ''Do Physicians Possess Market Power?'' Journal of Law and Economics 57, no. 1 (January 1, 2014).

[328] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo.*

[329] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Cost-Report.*

[330] *https://data.cms.gov/provider-summary-by-type-of-service.*

[331] *https://www.cms.gov/hospital-price-transparency.*

[332] *https://www.cms.gov/healthplan-price-transparency.*

[333] *https://www.cms.gov/newsroom/press-releases/hhs-releases-new-data-and-report-hospital-and-nursing-home-ownership.*

[334] *https://aspe.hhs.gov/sites/default/files/documents/4d960147d5fd8e2ea9af508f115ca7b7/aspe-datapoint-change-ownership-pecos.pdf.*

acquisitions, consolidations, or changes in ownership?

• Section 6401(a) of the Affordable Care Act established a requirement for all enrolled providers/suppliers to revalidate their Medicare enrollment information in PECOS under new enrollment screening criteria. In 2016, the Centers for Medicare & Medicaid Services (CMS) completed its initial round of revalidations and resumed regular revalidation cycles in accordance with 42 CFR 424.515.[335] Would data for transactions occurring before the 2016 CMS revalidation effort be useful for the public or researchers, even if such data may be less complete?

XX. Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services (84 FR 61142, 61446 through 61456) using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services.''[336] As part of the CY 2021 OPPS/ASC final rule with comment period, we added two additional service categories to the prior authorization process for certain hospital OPD services (85 FR 85866, 86236 through 86248). The regulations governing the prior authorization process for certain hospital OPD services are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89, with the specific service categories listed in § 419.83.

Paragraph (a)(1) of § 419.83 lists the specific service categories for which prior authorization must be obtained for service dates on or after July 1, 2020, which are: (i) Blepharoplasty; (ii) Botulinum toxin injections; (iii) Panniculectomy; (iv) Rhinoplasty; and (v) Vein ablation. Paragraph (a)(2) of § 419.83 lists two additional service categories for which prior authorization must be obtained for service dates on or after July 1, 2021, which are: (i) Cervical Fusion with Disc Removal; and (ii) Implanted Spinal Neurostimulators. Paragraph (b) states that CMS will adopt the list of hospital outpatient department-service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking. Additionally, paragraph (c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and paragraph (d) states that CMS may suspend the prior authorization process generally or for a particular service at any time by issuing a notification on the CMS website.

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Proposed Addition of a New Service Category

In accordance with § 419.83(b), we propose to require prior authorization for a new service category: Facet Joint Interventions. We propose adding the new service category at § 419.83(a)(3). We also propose that the prior authorization process for this additional service category would be effective for dates of services on or after March 1, 2023. As explained more fully below, the proposed addition of this service category is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services. Because we propose that prior authorization would be required for this service category at a later date than for the first seven service categories, we propose to revise paragraph (a)(3) to include this new service category and reflect the March 1, 2023 implementation date for the prior authorization requirement for this additional service category. Specifically, we propose that paragraph (a)(3) would read, ''[t]he Facet Joint Interventions service category requires prior authorization beginning for service dates on or after March 1, 2023.'' We also propose that existing paragraph (a)(3) be moved to paragraph (b) and that paragraph (b) be revised by modifying the title to read, ''Adoption of the list of services and technical updates.'' We also propose to re-designate the current paragraph (b) as subparagraph (b)(1). Subparagraph (b)(1) would read, ''CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking.'' As previously mentioned, current paragraph (a)(3) would be moved to new paragraph (b)(2) and read, ''Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.''

The proposed Facet Joint Interventions service category would consist of facet joint injections, medial branch blocks, and facet joint nerve destruction. Facet joint injections are procedures in which a practitioner injects a medication into the facet joints (the connections between the bones of the spine) to help diagnose the cause and location of pain and also to provide pain relief. Medial branch block is a procedure in which a medication is injected near the medial branch nerve connected to a specific facet joint to achieve pain relief. Facet joint nerve destruction (also known as nerve denervation) is a procedure that uses heat to destroy the small area of the facet joint nerve for pain management.

We propose that the list of proposed additional OPD services in the Facet Joint Interventions service category that would require prior authorization beginning on March 1, 2023 are those identified by the CPT codes in Table 79. For ease of review and brevity, we only include in the regulation text in proposed new § 419.83(a)(3) the name of the service category, but not the CPT codes that fall into that service category, which are listed in Table 79. Note that this is the same approach we took in establishing the initial five service categories in § 419.83(a)(1) and two additional service categories in § 419.83(a)(2). For ease of reference, we have included the 2020 Final List of Outpatient Services that Require Prior Authorization for the five initial service categories and the 2021 Final List of Outpatient Services that Require Prior Authorization for two additional service categories in Table 80. Again, we propose that the prior authorization process for the proposed additional service category would be effective for dates of service on or after March 1, 2023. We propose an effective date slightly earlier in the calendar year (compared to the July 1, 2020 and July 1, 2021 effective dates for the services categories previously added to the prior authorization regulation) because Medicare Contractors, CMS, and the OPD providers already have knowledge of and experience with the prior authorization process. Also, this new service category can be performed by some of the same provider types who furnish other services currently subject to the OPD prior authorization process, such as implanted spinal neurostimulators and cervical fusion with disc removal.

2. Basis for Proposing To Add a New Service Category

As part of our responsibility to protect the Medicare Trust Funds, we continue our routine analysis of data associated with all aspects of the Medicare

[335] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1605.pdf.*

[336] See also Correction Notice issued January 3, 2020 (85 FR 224).

program. This responsibility includes monitoring the total amount or types of claims submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting.

In proposing the addition of this new service category, we reviewed approximately 1 billion claims related to OPD services during the 10-year period from 2012 through 2021. We determined that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 0.6 percent. This equated to an increase from approximately 105 million OPD claims submitted for payment in 2012 to approximately 111 million claims submitted for payment in 2021. The 0.6 percent rate reflects a decrease when compared to the 2.8 percent rate identified in the CY 2021 OPPS/ASC proposed rule, when we looked at the period from 2007 through 2018. Our analysis also showed an average annual rate-of-increase in the Medicare allowed amount (the amount that Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) of 4.2 percent. Again, this is a decrease when compared to the 7.8 percent rate identified in the CY 2021 OPPS/ASC proposed rule for a slightly earlier timeframe. The decrease in the average annual increase in the claim volume and allowed amount from the increases noted in the CY 2021 OPPS/ASC proposed rule is likely due in part to the PHE as discussed in more detail below. We found that the total Medicare allowed amount for the OPD services claims processed in 2012 was approximately $48 billion and increased to $73 billion in 2021, while during this same 10-year period, the average annual increase in the number of Medicare beneficiaries per year was only 0.4 percent.

Our analysis of Integrated Data Repository (IDR [337]) data showed that, with regard to the facet joint interventions, CPT codes 64490–64495 and 64633–64636, claims volume increased by 47 percent between 2012 and 2021, reflecting a 4 percent average annual increase, which is higher than the 0.6 percent annual increase for all OPD services. For the facet joint injection and medial branch block services, CPT codes 64490–64495, we observed an increase of 27 percent between 2012 and 2021, reflecting a 2.5 percent average annual increase. This reflects an increase from approximately 136,000 claims submitted for payment in 2012 to approximately 173,775 claims submitted for payment in 2021. For the nerve destruction services, CPT codes 64633 through 64636, we observed an increase in volume of 102 percent between 2012 and 2021, which was an average annual increase of 7 percent. This accounts for an increase from approximately 48,000 claims submitted for payment in 2012 to approximately 97,000 claims submitted for payment in 2021. Both the facet joint injections/medial branch block CPT codes and nerve destruction CPT codes, with 2.5 and 7 percent annual increases, respectively, demonstrated higher average annual increases in claim submissions between 2012 and 2021 than the 0.6 percent annual increase for all OPD services over the same time period.

When analyzing the data, we took the COVID–19 Public Health Emergency (PHE) into consideration. As a result of the PHE, healthcare use and spending dropped sharply due to cancellations of elective and non-emergency care to increase hospital capacity and social distancing measures to reduce the community spread of the coronavirus. Consequently, the claims data for CY 2020 showed a significant decrease in volume compared to the previous year, which is likely due to the PHE. However, over the 9-year period of our analysis, services for facet joint interventions demonstrated increases. These volume increases led us to further research the reasons behind them, to determine if they were unnecessary.

The Department of Health and Human Services' Office of the Inspector General (OIG) has published multiple reports indicating questionable billing practices, improper Medicare payments, and questionable utilization of facet joint interventions. An OIG report published in 2020 identified $748,555 in improper payments out of $3.3 million in paid Medicare claims for facet joint injections with an audit period from January 1, 2017 through May 31, 2019. The OIG recommended that CMS and its contractors provide additional oversight on claims for facet joint injections to prevent additional improper payments.[338] In 2021, the OIG published a report on facet denervation procedures. During the audit period from January 2019 through 2020, the OIG reported that Medicare improperly paid physicians $9.5 million for selected facet joint denervation procedures. According to the OIG, these improper payments occurred because CMS's oversight was not adequate to prevent or detect improper payments for selected facet-joint denervation procedures.[339] Further, in March 2022, the Department of Justice reported on a $250 million health care fraud scheme that took place from 2007 to 2018 involving physicians from multiple states who allegedly subjected their patients to medically unnecessary facet joint injections in order to obtain illegal prescriptions for opioids. The physicians required patients to receive the facet joint injections due to their high reimbursement rates.[340] Both our data analysis and research show that the increases in volume for these procedures are unnecessary, and further program integrity action is warranted.

Our conclusion that increases in volume for facet joint services are unnecessary was based not only on the data specific to this service category, but also on a comparison of the rate of increase for the service category to the overall trends for all OPD services. We believe that comparing the utilization rate for the particular service category to the overall rate of growth for Medicare OPD services generally is an appropriate method for identifying unnecessary increases in volume, particularly where there are no legitimate clinical or coding reasons for the changes. We researched possible causes for the increases in volume that would indicate the services are increasingly necessary, but we did not find any explanations that would cause us to believe that was the case. We continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste, and abuse, including unnecessary increases in volume. We believe prior

[337] The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.*

[338] *https://oig.hhs.gov/oas/reports/region9/92003003.asp.*

[339] *https://oig.hhs.gov/oas/reports/region9/92103002.asp.*

[340] *https://www.justice.gov/opa/pr/16-defendants-including-12-physicians-sentenced-prison-distributing-66-million-opioid-pills.*

authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We request comments on the addition of this service category, and specifically request comments on the potential for any unintended clinical consequences from the addition of this service category.

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TABLE 79: 2023 PROPOSED LIST OF ADDITIONAL OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after March 1, 2023	
Code	Facet Joint Interventions
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

TABLE 80: FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2020	
Code	(i) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair[341]
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(ii) Botulinum Toxin Injection
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk

[341] CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

Code	(iv) Rhinoplasty, and related services[342]
20912	Cartilage graft; nasal septum
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(v) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
Beginning for service dates on or after July 1, 2021	

[342] CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

Code	(i) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators [343]
63650	Percutaneous implantation of neurostimulator electrode array, epidural

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XXII. Overall Hospital Quality Star Rating

A. Background

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars (85 FR 86193). The Overall Hospital Quality Star Rating was first introduced and reported on our Hospital Compare website in July 2016 [344] (now reported on its successor website at *https://www.medicare.gov/care-compare*) and has been refreshed multiple times, with the most current refresh planned for 2022.[345] [346] [347] [348] [349] [350] [351] In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86182), we finalized a methodology to calculate the Overall Hospital Quality Star Rating. We refer readers to section XVI (''Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years'') of the CY 2021 OPPS/ASC final rule with comment period and 42 CFR 412.190 for details.

In this proposed rule, we are: (1) providing information on the previously finalized policy for inclusion of quality measure data from Veteran's Health Administration (VHA) hospitals; (2) proposing to amend the language of § 412.190(c) to state that we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior twelve months; and (3) conveying that although CMS intends to publish Overall Hospital Quality Star Ratings in 2023, we may apply the suppression policy if applicable.

B. Veterans Health Administration Hospitals

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86197 and 86198), we finalized a policy to include Veterans Health Administration hospitals' (VHA hospitals) quality measure data for the purpose of calculating the Overall Hospital Quality Star Ratings beginning with the 2023 refresh. In that final rule, we also stated that we intended to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule (85 FR 48999). Since the publication of the CY 2021 OPPS/ASC final rule, we conducted an internal analysis from February 28, 2022, through March 30, 2022, with measure data from all VHA hospitals in the calculation of the Overall Hospital Quality Star Ratings methodology. The internal analysis included a period of confidential reporting and feedback during which VHA hospitals reviewed their Overall Hospital Quality Star Ratings internal analysis results, and in addition, further familiarized themselves with the Overall Hospital Quality Star Ratings methodology and had the opportunity to ask questions. All VHA hospitals were made aware of the internal analysis and were provided the opportunity to participate. For the internal analysis, the Overall Hospital Quality Star Ratings were calculated using VHA hospital measure data along with subsection (d) hospitals and CAHs. The internal analysis included the same measures used for the April 2021 refresh of Overall Hospital Quality Star Ratings on our public reporting website, Care Compare. At the time of the 2022 VHA internal analysis, VHA hospitals in each peer group reported a similar number of

[343] CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPPS/ASC final rule with comment period.

[344] Centers for Medicare & Medicaid Services. (2016, July 27). First Release of the Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from CMS.gov newsroom at: *https://www.cms.gov//newsroom//fact-sheets//first-release-overall-hospital-quality-star-rating-hospital-compare.*

[345] Centers for Medicare & Medicaid Services. (2016, May). Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.

[346] Centers for Medicare & Medicaid Services. (2016, October). Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.

[347] Centers for Medicare & Medicaid Services. (2017, October). Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.

[348] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from *qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[349] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from *qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[350] Centers for Medicare & Medicaid Services. (2017, November). Star Methodology Enhancement for December 2017 Public Release. Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[351] Centers for Medicare & Medicaid Services. (2022, May 17). Overall Hospital Quality Star Rating on Hospital Compare: July 2022 Updates and Specifications Report. Retrieved from *qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

measures when compared to non-VHA hospitals for most measure groups. VHA hospitals in the 5 measure group peer group reported a lower median number of Safety and Readmission measures. VHA hospitals in all three peer groups reported fewer measures in the Timely and Effective Care measure group. The measurement periods for VHA and non-VHA hospitals were the same, except for the HAI–1, HAI–2, PSI 04, PSI 90, and OP–22 measures. The specific performance periods for these measures were provided to VHA hospitals during the internal analysis. The reasons for the differing measure reporting periods are:

- The HAI–1 and HAI–2 measures were first publicly reported for VHA hospitals in July 2021, but only included one quarter of measure data. Therefore, we chose to use the next public reporting, April 2022, which included four quarters of these measures' data.
- For the PSI 04 and PSI 90 measures, we used measure data that was publicly reported in July 2021. VHA hospitals first publicly reported these measures in October 2020; however, a different software was used for the measure calculations than the software used to calculate subsection (d) hospitals and CAHs measure data. We chose to use measure data publicly reported in 2021 for better comparison.
- For the OP–22 measure, VHA hospitals began submitting their measure data in January 2021 for public reporting.
- For the HIP/KNEE measures (total hip arthroplasty (THA) and total knee arthoroplasty (TKA)), we used measure data that was publicly reported in October 2020. This data did not initially include VHA hospitals, so we recalculated to include them. The recalculated results including VHA hospitals was not publicly reported until July 2021.

Using these data from the internal analysis, we compared 2021 Overall Hospital Quality Star Ratings scores for non-VHA hospitals before and after adding VHA hospitals to Overall Hospital Quality Star Ratings. 119 out of 171 VHA hospitals met the requirements to receive a Star Rating. This increased the number of hospitals receiving a star rating from 3,355 to 3,474. The distribution of Star Ratings was nearly identical for VHA and non-VHA hospitals. As part of the Overall Hospital Quality Star Ratings methodology, hospitals are assigned to peer groups based on the number of measure groups with at least three measures. Peer group assignments were similar across VHA and non-VHA hospitals. In Peer Group 3, assignments were 12 percent VHA vs. 10 percent non-VHA; in Peer Group 4, assignments were 25 percent VHA vs. 16 percent non-VHA; and in Peer Group 5, assignments were 63 percent VHA vs. 74 percent non-VHA). 3,119 (93 percent) non-VHA hospitals maintained the same number of stars after adding VHA hospitals to 2021 Overall Hospital Quality Star Ratings. For the 236 non-VHA hospitals with a different star rating, 23 gained a star and 213 lost a star. No hospital gained or lost more than one star. As with any update to either the underlying measures or the Overall Hospital Quality Star Ratings methodology, we expect that some hospitals would shift star rating categories. However, for this internal analysis, over 90 percent of non-VHA hospitals did not experience a change in their Overall Hospital Quality Star Ratings score, which is consistent with prior changes to the measures or methodology in our experience. As previously finalized, we intend to include VHA hospitals in future Overall Hospital Quality Star Ratings.

C. Frequency of Publication and Data Used

We are also proposing to amend our policy regarding the data periods used to refresh Overall Hospital Quality Star Ratings. In the CY 2021 OPPS final rule with comment period, we stated that ''we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior year'' to refresh Overall Hospital Quality Star Ratings (85 FR 86202). Since adopting that policy, it has come to our attention that this wording could be confusing. We intended for the phrase ''within the prior year'' to refer to any time within the prior 12 months, and not to a Care Compare refresh from the prior calendar year. Therefore, we are proposing to change § 412.190 (c) to state ''The Overall Star Rating are published once annually using data publicly reported on Hospital Compare or its successor website from a quarter within the previous 12 months.'' For example, for the Overall Hospital Quality Star Ratings in July 2023, we would use any Care Compare refreshes from the previous 12 months: July 2023, April 2023, January 2022, October 2022, or July 2022.

We invite public comments on this proposal.

D. Overall Hospital Quality Star Ratings Suppression

During development of the Overall Hospital Quality Star Ratings, we established guiding principles to use methods that are scientifically valid, inclusive of hospitals and measure information, account for the heterogeneity of available measures and hospital reporting, and accommodate changes in the underlying measures (85 FR 86193).[352] Overall Hospital Quality Star Ratings aggregates performance on underlying measures adopted under certain CMS quality programs, so any changes or updates to the measures from those programs are already included (85 FR 86194).[353] We continue to believe that the robustness of Overall Hospital Quality Star Ratings to changes in the underlying measures enables the methodology to maintain validity even when there are changes in the health system or underlying measure data (85 FR 86203 through 86205).

We recognize that there may be some concerns with publishing Overall Hospital Quality Star Ratings if the underlying measures reflect some aspect of extenuating circumstances, for example, skewed data or performance related to treating patients with COVID–19. However, we want to balance that with providing important quality information to Medicare beneficiaries and the public during times when hospital care is critical. The goal of the Overall Hospital Quality Star Ratings is to summarize hospital quality information in a way that is simple and easy for patients to understand to increase transparency and empower patients to make more informed decisions about their healthcare.

Although Overall Hospital Quality Star Ratings will have been refreshed twice (*i.e.,* in 2021 and 2022) since the emergence of COVID–19, almost all measures included in both Overall Hospital Quality Star Ratings refreshes used pre-COVID–19 data to calculate both the 2021 and 2022 Overall Star Ratings. This is because we issued a nationwide Extraordinary Circumstance Exception (ECE) for hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 Public Health Emergency (PHE). The ECE can be found at this website: *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-*

[352] Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1*.

[353] Centers for Medicare & Medicaid Services. (2017, November). Star Methodology Enhancement for December 2017 Public Release. Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources*.

based-purchasing-programs.pdf. Among other requirements, this ECE exempted data reporting requirements for Q1 and Q2 2020 data, including excluding the use of claims data and data collected through the Centers for Disease Control's (CDC) National Healthcare Safety Network (NHSN) for this data period.[354] Because the ECE only applied through Q2 2020, beginning July 1, 2020, any subsequent measure data collected from these programs would be incorporated into the Overall Hospital Quality Star Ratings. This would include measurement periods that are either partially or fully concurrent with the COVID–19 PHE.

If a measure is considered valid and reliable enough to be reported on Care Compare then it meets the criteria to be included in Overall Hospital Quality Star Ratings calculations (85 FR 86193 through 86236). This remains true even for measures that were suppressed in certain programs due to the impact of COVID–19 (86 FR 45301 through 45304). Consistent with this policy, we will continue to include measures in the Overall Hospital Quality Star Ratings that might have been suppressed in the Hospital Value-Based Purchasing, Hospital-Acquired Condition Reduction, and Hospital Readmissions Reduction Programs but are still publicly reported (86 FR 44778 through 44779).

In the CY 2021 OPPS/ASC rule with comment period (85 FR 48996 through 49027), we finalized that we will allow for suppression, but only in limited circumstances. Specifically, for the Overall Hospital Quality Star Rating beginning with the CY 2021 and for subsequent years, we adopted a policy that we would consider suppressing the Overall Star Rating only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS or when CMS is at fault, including but not limited to when—

- There is an Overall Star Rating calculation error by CMS;
- There is a systemic error at the CMS quality program level that substantively affects the Overall Hospital Star Rating calculation. For example, there is a CMS quality program level error for one or more measures included within the Overall Star Rating due to incorrect data processing or measure calculations that affects a substantial number of hospitals reporting those measures. We note that we would strive to first correct systemic errors at the program level per program policies and then recalculate the Overall Star Rating, if possible; or
- A Public Health Emergency substantially affects the underlying measure data.

This is codified at § 412.190(f)(1). Although CMS intends to publish the Overall Hospital Quality Star Rating in 2023, CMS may exercise the authority described above should the COVID–19 PHE substantially affect the underlying measure data.

XXII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C, by adding a column titled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). For CY 2023, we propose to retain these columns, updated to reflect the amount of the 2023 inpatient deductible. In the CY 2022 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' where we flagged through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2023, we propose to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in CY 2023.

In addition, for CY 2023, we propose to update a column titled ''Drug Pass-Through Expiration during Calendar Year'' to include devices, so that the column reads ''Drug and Device Pass-Through Expiration during Calendar Year'' where we propose to flag through the use of an asterisk, each drug and device for which pass-through payment would be expiring during the calendar year on a date other than December 31.

To view the Addenda to this proposed rule pertaining to proposed CY 2023 payments under the OPPS, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''CMS–1772–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder titled ''2023 NPRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2023 payments under the ASC payment system, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''CMS–1772–P'' from the list of regulations. The ASC Addenda to this proposed rule are contained in a zipped folder titled ''Addendum AA, BB, DD1, DD2, EE, and FF'' in the related links section at the bottom of the page.

XXIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 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 title 44 of the U.S. Code, as added by section 2 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

[354] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*.

B. ICRs for the Hospital OQR Program

1. Background

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2011 through CY 2022 OPPS/ASC final rules (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; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156; 84 FR 61468 through 61469; 85 FR 86266 through 86267; and 86 FR 63961 through 63968, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs. The ICRs associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109, which expires on February 28, 2025.

In the CY 2022 OPPS/ASC final rule with comment period, our burden estimates were based on an assumption of 3,300 hospitals (86 FR 63961). For this proposed rule, we propose to update our assumption to 3,350 hospitals based on recent data from the CY 2022 payment determination which reflects a closer approximation of the total number of hospitals reporting data for the Hospital OQR Program.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52617), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. In BLS' most recent set of National Occupational Employment and Wage Estimates published on March 31, 2022, this occupation title has been removed. As a result, we now utilize the ''Medical Records Specialists'' occupation title. The BLS describes Medical Records Specialists as those responsible for compiling, processing, and maintaining medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the healthcare system and classifying medical and healthcare concepts, including diagnosis, procedures, medical services, and equipment, into the healthcare industry's numerical coding system; [355] therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data from the BLS' May 2021 Occupational Employment and Wages data reflects a median hourly wage of $23.23 per hour for a Medical Records Specialists. We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52617). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can 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 ($23.23 × 2 = $46.46) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. Summary

In section XV.B.4 of this proposed rule, we propose to: (1) change the Cataracts: Improvement in Patient's Visual Function within 90 days Following Cataract Surgery measure (OP–31) to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) add an additional targeting criterion to the validation selection policy beginning with the CY 2023 reporting period; and (3) align the patient encounter quarters with the calendar year and update the data submission deadlines for each of these quarters beginning with the Q2 2023 reporting period.

3. Estimated Burden of Hospital OQR Program Requirements for the CY 2025 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for OP–31: Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63845 through 63846), we finalized to require this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66947 through 66948) and estimated that 20 percent of hospitals would elect to report it annually (79 FR 67014). As discussed in section XV.B.5.b of this proposed rule, we propose to change this measure to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. We continue to estimate it will require hospitals 10 minutes once annually to report this measure using a CMS web-based tool. As a result of this proposal, we estimate only 20 percent of hospitals would voluntarily submit data, which results in a total annual burden estimate of 112 hours (3,350 hospitals × 20 percent × 0.1667 hours) at a cost of $5,188 (112 hours × $46.46/hour). In addition to reporting the measure, for hospitals that chose to voluntarily submit, we also require hospitals to perform chart abstraction and estimate that each hospital would spend 2.92 minutes (0.049 hours) per case per measure to perform this activity. In the CY 2022 OPPS/ASC final rule with comment period, we used an estimate of 25 minutes per case per measure (86 FR 63963). Upon review, this estimate was erroneous, therefore we are correcting our assumption to 2.92 minutes (0.049 hours) per case per measure as finalized in the CY 2016 OPPS/ASC final rule (80 FR 70582). The currently approved burden estimate assumes 242 cases per measure. For chart abstraction, we estimate an annual burden of 12 hours (0.049 hours × 242 cases) at a cost of $549 (12 hours × $46.46/hour) per hospital and a total annual burden of 7,891 hours (3,350 hospitals × 20 percent × 12 hours) at a cost of $368,028 (7,891 hours × $46.46/hour) for all participating hospitals. In aggregate, we estimate a total annual burden of 8,003 hours (112 hours + 7,891 hours) at a cost of $373,216 ($5,188 + $368,028) for all hospitals. This is a decrease of 325,847 hours and $15,138,852 per year from the currently approved estimate due to the 80 percent of hospitals we assume will no longer report this measure, the updated assumption of the number of hospitals participating in the Hospital OQR Program, the updated burden estimate for chart abstraction, and the updated wage rate.

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on February 28, 2025.

b. Information Collection Burden Estimate for the Addition of an Additional Targeting Criterion to the Validation Selection Policy

In section XV.B.4 of this proposed rule, we propose to adopt an additional targeting criterion to the validation

[355] *https://www.bls.gov/oes/current/oes292072.htm* (Accessed June 23, 2022). The hourly rate of $46.46 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

selection policy beginning with the CY 2023 reporting period/CY 2025 payment determination. We also propose to codify this targeting criterion at § 419.46(f)(3). We do not believe this proposal would increase reporting burden, because it changes neither the total number of hospitals required to submit data nor the amount of data hospitals selected for validation would be required to submit.

c. Information Collection Burden Estimate for the Alignment of Patient Encounter Quarters With the Calendar Year

In section XV.B.4.b of this proposed rule, we propose to align patient encounter quarters with the calendar year (January through December), beginning with the CY 2026 payment determination and subsequent years. We do not anticipate that this proposal, if finalized, would result in any increase in information collection burden because it would not change the amount of data hospitals would be required to submit.

d. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938–1109 which expires on February 28, 2025 we estimate that the updated assumptions and proposals in this proposed rule will result in a decrease of 325,847 hours annually for 3,350 OPPS hospitals for the CY 2025 reporting period/CY 2027 payment determination and subsequent years. The total cost decrease related to this information collection is approximately -$15,138,852 (325,847 hours × $46.46/hour) (which also reflects use of an updated hourly wage rate as previously discussed). Table 81 summarizes the estimated total burden change compared to our currently approved information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109. We are not proposing any changes for the CY 2024 reporting period/CY 2026 payment determination, therefore the previously finalized burden estimates for the CY 2024 reporting period/CY 2026 payment determination remain unchanged.

TABLE 81: SUMMARY OF PROPOSED ESTIMATED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Payment Determination and Subsequent Years							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Voluntary Reporting of OP-31 Measure	10	1	670	1	0.167	112	550	-438
Chart Abstraction for OP-31 Measure	2.9	1	670	242	12	7,891	333,300	-325,409
	Total Change in Information Collection Burden Hours: -325,847							
	Total Cost Estimate: Updated Hourly Wage ($46.46) x Change in Burden Hours (-325,847) = **-$15,138,852**							

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, CY 2019, CY 2020, CY 2021, and CY 2022 OPPS/ASC final rules (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; 84 FR 61469; 85 FR 86267; and 86 FR 63968 through 63971, respectively) for detailed discussions of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2023 payment determinations are currently approved under OMB control number 0938–1270, which expires on July 31, 2024.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52619 through 52620), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the BLS, to calculate our burden estimates for the ASCQR Program. In BLS' most recent set of National Occupational Employment and Wage Estimates published on March 31, 2022, this occupation title has been removed. As a result, we now utilize the ''Medical Records Specialists'' occupation title. The BLS describes Medical Records Specialists as those responsible for compiling, processing, and maintaining medical records of hospital and clinic patients in a manner consistent with

medical, administrative, ethical, legal, and regulatory requirements of the healthcare system and classifying medical and healthcare concepts, including diagnosis, procedures, medical services, and equipment, into the healthcare industry's numerical coding system;[356] therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the ASCQR Program. The latest data from the BLS' May 2021 Occupational Employment and Wages data reflects a median hourly wage of $23.23 per hour for a Medical Records Specialists. We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52619 through 52620). This by necessity is a rough adjustment, both because fringe benefits and overhead costs can 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 ($23.23 × 2 = $46.46) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on an analysis of the CY 2020 payment determination data, we found that of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 3,494 were required to participate in the Program and did so. In addition, 689 ASCs that were not required to participate due to having low Medicare claims volume (less than 240), did so, for a total of 4,183 participating facilities. As noted in section XXV.C.5.a of the ''Regulatory Impact Analysis'' of this proposed rule, for the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program's ECE policy in consideration of the COVID–19 PHE; 3,957 of these ASCs would have been required to participate without the PHE exception. Therefore, we estimate that 3,957 plus 689, or 4,646, ASCs will submit data for the ASCQR Program for the CY 2023 payment determination unless otherwise noted.

2. Summary

In section XV.B.4 of this proposed rule, we propose to change the Cataracts: Improvement in Patient's Visual Function within 90 days Following Cataract Surgery measure (ASC–11) to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination.

3. Estimated Burden of ASCQR Program Requirements for the CY 2025 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for Proposal To Change ASC–11: Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure From Mandatory to Voluntary

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63886 through 63887), we finalized to require this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985) and estimated that 20 percent of ASCs would elect to report it annually (79 FR 67016). As discussed in section XV.B.5.b of this proposed rule, we propose to change the ASC–11 measure to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. We continue to estimate it will require ASCs 10 minutes once annually to report this measure using a CMS web-based tool. As a result of this proposal, we estimate only 20 percent of ASCs would voluntarily submit data, which results in a total annual burden estimate for all participating ASCs of 155 hours (4,646 ASCs × 20 percent × 0.1667 hours) at a cost of $7,194 (115 hours × $46.46/hour). In addition to reporting the measure, for ASCs that chose to voluntarily submit, we also require ASCs to perform chart abstraction for a minimum required sample size of 63 cases. In the CY 2022 OPPS/ASC final rule, we estimated that each ASC would spend 15 minutes (0.25 hours) per case to perform this activity (86 FR 63969). However, upon review, we believe the effort involved with this activity is similar to what is required for the OP–31 measure in the Hospital OQR Program, therefore, we are updating our assumption to 2.92 minutes (0.049 hours) per case per measure. Therefore, we estimate an annual burden of 3.1 hours (0.049 hours × 63 cases) at a cost of $142 (3.1 hours × $46.46/hour) per ASC and a total annual burden of 2,848 hours (4,646 ASCs × 20 percent × 3.1 hours) at a cost of $132,333 (2,848 hours × $46.46/hour) for all participating ASCs. In aggregate, we estimate a total annual burden of 3,003 hours (155 hours + 2,848 hours) at a cost of $139,527 ($7,194 + $132,333) for all ASCs. This is a decrease of 72,107 hours and $3,350,091 per year from the currently approved estimate due to the 80 percent of ASCs we assume would no longer report this measure, the updated burden estimate per case per measure, and the updated wage rate.

b. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, under OMB control number 0938–1270 which expires on July 31, 2024, we estimate that the policies promulgated in this proposed rule would result in a decrease of 72,107 hours annually for 4,646 ASCs for the CY 2025 reporting period/CY 2027 payment determination and subsequent years. The total cost decrease related to this information collection is approximately $3,350,091 (72,107 hours × $46.46/hour). Table 82 summarizes the total burden change compared to our currently approved information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270.

[356] *https://www.bls.gov/oes/current/oes292072.htm* (Accessed June 23, 2022). The hourly rate of $42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

TABLE 82: SUMMARY OF PROPOSED ESTIMATED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Payment Determination and Subsequent Years							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Voluntary Reporting of ASC-11 Measure	10	1	929	1	0.167	155	774	-619
Chart Abstraction for ASC-11 Measure	2.9	1	929	63	3.1	2,848	74,336	-71,488
	Total Change in Information Collection Burden Hours: -72,107							
	Total Cost Estimate: Updated Hourly Wage ($46.46) x Change in Burden Hours (-72,107) = **-$3,350,091**							

D. ICRs for Rural Emergency Hospitals (REH) Physician Self-Referral Law Update

As discussed in section XVIII.E of this proposed rule, we propose to revise certain existing exceptions applicable to compensation arrangements involving specific types of providers to make them applicable to compensation arrangements to which an REH is a party. Specifically, we propose to revise the exceptions for physician recruitment at § 411.357(e), obstetrical malpractice insurance subsidies at § 411.357(r), retention payments in underserved areas at § 411.357(t), electronic prescribing items and services at § 411.357(v), assistance to compensate a nonphysician practitioner at § 411.357(x), and timeshare arrangements at § 411.357(y) to also permit an REH to provide remuneration to a physician (or an immediate family member of a physician) if all requirements of the applicable exception are satisfied. All of the proposed revisions would ensure that exceptions that may already be utilized by existing hospitals eligible to undergo conversion to an REH remain available to REHs.

The existing exceptions at § 411.357(e), (r), (t), (v), (x), and (y) each require that the compensation arrangements to which the exceptions apply be documented in a writing signed by the parties. The existing exception at § 411.357(t)(2) also requires a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center, or physician organization that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The existing exception at § 411.357(x) also requires that records of the actual amount of remuneration provided by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years. We are not proposing any changes to the existing writing, signature, or record retention requirements. The burden associated with writing and signature requirements would be the time and effort necessary to prepare written documents and obtain signatures of the parties. The burden associated with record retention requirements would be the time and effort necessary to compile and store the records.

While the writing, signature, and record retention requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons without Federal regulation during the normal course of their activities. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others and retain these documents in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing, signature, and record retention requirements should be considered usual and customary business practices.

E. ICRs for Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services. (84 FR 61142, 61446 through 61456).[357] As part of the CY 2021 OPPS/ASC final rule with comment period we added additional service categories to the prior authorization process (85 FR 85866, 86236 through 86248). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

[357] See also Correction Notice issued January 3, 2020 (85 FR 224).

In accordance with § 419.83(b), we propose to require prior authorization for a new service category: Facet Joint Interventions. We propose adding the service category to § 419.83(a)(3). We also propose that the prior authorization process for the additional service category would be effective for dates of services on or after March 1, 2023. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the new category, Facet Joint Interventions, will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task will be 30 minutes, which is equivalent to that for normal prepayment or post payment medical review. We anticipate that most prior authorization requests will be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to the proposed March 1, 2023 start date, the first year of the prior authorization for the new service category would only include 10 months. Based on CY 2019 data, we estimate that for those first 10 months there would be 69,501 initial requests mailed during the year. In addition, we estimate there would be 22,805 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $461,532 (92,306 mailed requests × $5). Based on CY 2019 data for the new service category, we estimate that annually there would be 83,401 initial requests mailed during a year. In addition, we estimate there would be 27,366 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total annual mailing cost is estimated to be $553,838 (110,786 mailed requests × $5). We also estimate that an additional 3 hours per provider would be required for attending educational meetings, training staff on what services require prior authorization, and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS information, we estimate an average clerical hourly rate of $17.13 with a loaded rate of $34.26. The prior authorization program for the new service category would not create any new documentation or administrative requirements. Instead, it would just require the same documents needed to support claim payments to be submitted earlier in the claim process. The estimate uses the clerical rate since we do not believe that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. CMS believes providers would have provided education to their staff on what services are included in the prior authorization process. Following this education, the staff would know which services need prior authorization and would not need additional time or resources to determine if a service requires prior authorization. We estimate that the total number of submissions for the first year (10 months) will be 307,688 (215,382 submissions through fax or electronic means + 92,306 mailed submissions). Therefore, we estimate that the total burden for the first year (10 months) for the new service category, allotted across all providers, would be 161,305 hours (.5 hours × 307,688 submissions plus 3 hours × 2,487 providers for education). The burden cost for the first year (10 months) is $5,987,841 (161,305 hours × $34.26 plus $461,532 for mailing costs). In addition, we estimate that the total annual number of submissions would be 369,225 (258,458 submissions through fax or electronic means + 110,768 mailed submissions). The annual burden hours for the new service category, allotted across all providers, would be 192,074 hours (.5 hours × 369,225 submissions plus 3 hours × 2,487 providers for education). The annual burden cost would be $7,134,276 (192,074 hours × $34.26 plus $553,838 for mailing costs). For the total burden and associated costs for the new service category, we estimate the annualized burden to be 181,818 hours and $6,752,131 million. The annualized burden is based on an average of 3 years, that is, 1 year at the 10-month burden and 2 years at the 12-month burden. The ICR approved under OMB control number 0938–1368 would be revised and submitted to OMB for approval.

Table 83 below is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule.

TABLE 83: TOTAL BURDEN FOR NEW SERVICE CATEGORY

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process	+181,818	+$6.8 million

* Numbers rounded.

F. ICRs for Proposed Payment Adjustments for Domestic NIOSH-Approved Surgical N95 Respirators

In section X.H of this proposed rule, we propose IPPS and OPPS payment adjustments for the additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. The proposed payment adjustments would be based on the IPPS and OPPS shares of the estimated difference in the reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic ones. As discussed in section X.H of this proposed rule, in order to calculate the N95 payment adjustment for each eligible cost reporting period, we propose to create a new cost report form to collect additional information from hospitals.

Specifically, we propose to collect the following: (1) total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital; (2) total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital; (3) total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital; and (4) total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital. This information would be used along with other information already collected on the cost report to calculate an IPPS payment adjustment amount and an OPPS payment adjustment amount. This new cost report worksheet may be submitted by a provider of service as part of the annual filing of the cost report and make available to its contractor and CMS, documentation to substantiate the data included on this Medicare cost report worksheet. These proposed documentation requirements are based on the recordkeeping requirements at current § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare.

The burden associated with this proposal would be the time and effort necessary for the provider to locate and obtain the relevant supporting documentation to report the quantity and aggregate costs of domestic NIOSH-approved surgical N95 respirators and non-domestic NIOSH-approved surgical N95 respirators purchased by hospital for the period.

G. ICRs for Proposed REH Provider Enrollment Requirements

As stated earlier in section XIX.C.1 of this proposed rule, proposed § 424.575, as well as existing § 424.510(a)(1) and (d)(1), would require REHs to complete and submit the applicable enrollment application, which, for REHs, would be the Form CMS–855A (OMB control number 0938–0685). The only impacts associated with our proposed REH enrollment policies are those concerning the submission of a Form CMS–855A change of information application to convert from a CAH or hospital (as defined in section 1886(d)(1)(B) of the Act) to an REH. Per a North Carolina Rural Health Research Program [358] study (and as stated in the CMS proposed rule titled ''Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital CoP Updates,'' published in the **Federal Register** on July 6, 2022 (87 FR 40350), we estimate that 68 REHs would convert from either a CAH or section 1886(d)(1)(B) hospital. (However, as we did in the aforementioned July 6, 2022 proposed rule, we acknowledge that the number of conversions could be less than or significantly greater than this estimate.) For purposes of these calculations, we assume that all of these facilities would do so within the first year of our proposed requirements.

Form CMS–855A applications are typically completed by the provider's office or administrative staff. According to the most recent BLS wage data for May 2021, the mean hourly wage for the general category of ''Office and Administrative Support Workers, All Other'' (the most appropriate BLS category for owners) is $20.47 (*see http://www.bls.gov/oes/current/oes_nat.htm#43-0000*). With fringe benefits and overhead, the figure is $40.94. This would result in an estimated Year 1 burden involving proposed § 424.575 of 68 hours (68 applications × 1 hour) at a cost of $2,784. Over a 3-year period, this results in an annual burden of 23 hours at a cost of $928.

The burden associated with this proposed requirement will be included as part of a resubmission of the information collection previously approved under 0938–0685. In addition to the announcement in this rule, we will also be publishing the required 60-day and 30-day notices to formally announce the aforementioned resubmission request and to both inform the public on where to find the revised PRA package for review and where to submit comments.

[358] *https://www.shepscenter.unc.edu/product/how-many-hospitals-might-convert-to-a-rural-emergency-hospital-reh/.*

XXIV. 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 consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXV. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2023. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2021, through and including December 31, 2021, and processed through December 31, 2021, and June 2020 HCRIS information with cost reporting periods prior to the PHE, as discussed in section X.B of this proposed rule with comment period.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2023, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2023. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. We believed that this policy would help stabilize the differential between OPPS payments and ASC payments, given that the CPI–U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

In this proposed rule we are also requesting information on possible alternative methodologies for counting organs for transplant hospitals and organ procurement organizations to calculate Medicare's share of organ acquisition costs, but we are not making any proposals at this time. We propose to exclude research organs from total usable organs used in the calculation of Medicare's share of organ acquisition costs and require a cost offset, but we are unable to estimate the extent to which the research organ proposal may impact the cost of research organs and the costs to Medicare. We also propose to clarify that certain costs associated with cardiac death are covered as organ acquisition costs but we do not anticipate an impact from this proposal. Therefore, there is no impact from the organ acquisition proposals in this proposed rule.

B. Overall Impact of Provisions of This Proposed Rule

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 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). This section of this proposed rule contains the impact and other economic analyses for the provisions we propose for CY 2023.

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. 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 hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).'' 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 the provisions 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.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2023, compared to CY 2022, due only to the proposed changes to the OPPS in this proposed rule, would be approximately $1.79 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2023, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2023 would be approximately $86.2 billion, which is approximately $6.2 billion higher than estimated OPPS expenditures in CY 2022. Because the provisions of the OPPS are part of a proposed rule that 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 84 of this proposed rule displays the distributional impact of the CY 2023 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that we formally propose for CY 2023 that drugs and biologicals that are acquired under the 340B Program would be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable. The impacts on hospital rates as a result of this formal proposal are reflected in the discussion of the estimated effects of this proposed rule. However, we fully expect to revert to our previous policy of paying ASP plus 6 percent for drugs acquired under the 340B program and anticipate budget neutralizing the increase in payments for these drugs consistent with our longstanding policy of offsetting increases or decreases in particular payments through an adjustment to the OPPS conversion factor.

We estimate that the proposed update to the conversion factor and other budget neutrality adjustments would increase total OPPS payments by 2.7 percent in CY 2023. 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, the formal proposed continuation of payment policy for separately payable drugs acquired under the 340B program, and the proposed payment adjustment for cancer hospitals would not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2022 and CY 2023, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, pass-through payments, the application of the frontier State wage adjustment, 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, the proposed exception for rural sole community hospitals from the clinic visit policy when provided at off-campus provider based departments, and the proposed payment adjustment for the additional resource costs for domestic NIOSH-approved surgical N95 respirators would increase total estimated OPPS payments by 2.9 percent.

We estimate the total increase (from changes to the ASC provisions in this

proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2023 compared to CY 2022, to be approximately $130 million. Tables 85 and 86 of this proposed rule display the redistributive impact of the CY 2023 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2023 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2023 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the website, select ''regulations and notices'' from the left side of the page and then select ''CMS–1772–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 84 of this proposed rule. 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 or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Payment Policy for Drugs and Biologicals Obtained Under the 340B Program

In section V.B of this proposed rule, we discuss our formal proposal to adjust the payment amount for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. Rural SCHs, children's hospitals, and PPS-exempt cancer hospitals which we propose continue to be excepted from this payment policy in CY 2023. Specifically, in this proposed rule for CY 2023, for hospitals paid under the OPPS (other than those that are proposed to be excepted for CY 2023), we formally propose to pay for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent. Because we formally propose to continue current Medicare payment policy for CY 2022, the budget neutrality adjustment does not reflect a change as a result of the 340B drug payment policy.

However, in light of the Supreme Court's recent decision in *American Hospital Association,* we fully anticipate reverting to our prior policy of paying for drugs at ASP+6 percent, regardless of whether they were acquired through the 340B program.[359] We also fully expect that when we revert to paying for drugs acquired through the 340B program at ASP+6 percent, we will budget neutralize that increase consistent with the OPPS statute and our longstanding policy by making a corresponding decrease to the OPPS conversion factor to account for the increase in payment rates for these drugs. As set forth earlier in this proposed rule, to ensure budget neutrality under the OPPS, after applying this alternative payment methodology for drugs and biologicals purchased under the 340B Program, we currently estimate that we would apply an offset of approximately $1.96 billion to decrease the OPPS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor, for a revised conversion factor of $83.279. Accordingly, we have included information with this proposed rule that presents the potential impact on OPPS providers and payment rates if we finalize our anticipated alternative policy to pay for drugs acquired through the 340B program at ASP plus 6 for CY 2023. We are providing a file comparing the budget neutrality and certain other ratesetting adjustments calculated associated with this potential change. Finally, we are making available other proposed rule supporting data files based on this potential change that we ordinarily would have provided if we had had sufficient time to formally propose paying for 340B drugs at ASP plus 6 percent, including: the OPPS impact file, the impact table, addenda, and budget neutrality factors. We refer the reader to the CMS website for this proposed rule for more information on where these supplemental files can be found. Public comments on the budget neutrality adjustment are welcome and will be carefully considered.

[359] Given the timing of the Supreme Court's decision in *American Hospital Ass'n* v. *Becerra*, we lacked the necessary time to account for that decision before issuing this proposed rule and, for that reason alone, we formally propose here to continue our former policy.

c. Effects of the Proposed IPPS and OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators

As discussed in section X.H of the preamble of this proposed rule, we propose IPPS and OPPS payment adjustments for the additional resource costs that hospitals incur in procuring domestic NIOSH-approved surgical N95 respirators. We propose that the payment adjustments would commence for cost reporting periods beginning on or after January 1, 2023.

For the IPPS, we propose to make this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1886(d)(5)(I) of the Act. To further support the strategic policy goal of sustaining a level of supply resilience for domestic NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency, we are not proposing to make the IPPS payment adjustment budget neutral under the IPPS. The data currently available to calculate a spending estimate for CY 2023 under the IPPS is limited. However, we believe the methodology described next to calculate this spending estimate under the IPPS for CY 2023 is reasonable based on the information available.

To calculate the estimated total spending associated with this policy under the IPPS we multiplied together estimates of the following:

(1) Estimate of the total number of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023.

(2) Estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators.

(3) Estimate of the percentage of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023 that are domestic.

For purposes of this estimate, we believe it is reasonable to assume that on average approximately one NIOSH-approved surgical N95 respirator is used for every day a beneficiary is in the hospital. The FY 2021 MedPAR claims data used for ratesetting in the FY 2023 IPPS/LTCH proposed rule accounted for approximately 7.2 million IPPS discharges and 38.3 million Medicare covered days. Therefore, for CY 2023, we are estimating that the total number of NIOSH-approved surgical N95 respirators (both domestic and non-domestic) used in the treatment of IPPS patients will be 38.3 million. Based on available data, our best estimate of the difference in the average unit costs of domestic and non-domestic NIOSH-approved surgical N95 respirators is $0.20.

It is particularly challenging to estimate the percentage of NIOSH-approved surgical N95 respirators that will be used in the treatment of IPPS patients in CY 2023 that will be domestic. The OMB's Made in America Office recently conducted a data call on capacity in which several entities attested to being able to supply 3.6 billion NIOSH-approved and Berry-compliant surgical N95 respirators annually in the future if there were sufficient demand. We recognize that it may take time for this capacity to be fully reflected in hospital purchases. Therefore, although this would be sufficient capacity to supply the entire hospital industry if it were to be available and focused on this segment of the marketplace in 2023, we believe it is reasonable to assume that this will not happen instantaneously and hospitals in aggregate may in fact be able to purchase less than half of their NIOSH-approved surgical N95 respirators as domestic in 2023. Therefore, for purposes of this IPPS spending estimate, we set the percentage of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023 that are domestic to 40 percent, or slightly less than half. We estimate that total CY 2023 IPPS payments associated with this policy will be $3.1 million (or 38.3 million covered days * $0.20 * 40 percent).

For the OPPS, we propose to make this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1833(t)(2)(E) of the Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. Consistent with this authority, the proposed OPPS payment adjustment would be budget neutral. In section X.H of the preamble of this proposed rule, we estimate that total CY 2023 OPPS payments associated with this policy will be $8.3 million. This represents approximately 0.01 percent of the OPPS, which we propose to budget neutralize through an adjustment to the OPPS conversion factor.

d. Estimated Effects of OPPS Changes on Hospitals

Table 84 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-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 84, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2023, we propose to continue to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B of this 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 applicable to the OPD fee schedule for CY 2023 is 3.1 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.1 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.4 percentage point for CY 2023 (which is also the productivity adjustment for FY 2023 in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28403)), resulting in the CY 2023 OPD fee schedule increase factor of 2.7 percent. We propose to use the OPD fee schedule increase factor of 2.7 percent in the calculation of the CY 2023 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 84 of this proposed rule.

To illustrate the impact of the CY 2023 changes, our analysis begins with a baseline simulation model that uses the CY 2022 relative payment weights, the FY 2022 final IPPS wage indexes that include reclassifications, and the final CY 2022 conversion factor. Table 84 shows the estimated redistribution of the increase or decrease in payments for CY 2023 over CY 2022 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2022 and CY 2023 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.7 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated differential impact of the proposed rural SCH exception to the Off Campus Provider Based Department Visits Policy (Column 5); the estimated impact taking into account all payments for CY 2023 relative to all payments for CY 2022, including the impact of changes in estimated outlier payments, changes to the pass-through payment estimate, the proposed change to except rural sole community hospitals from the clinic visit policy when provided at campus provider based departments, and the proposed payment adjustment for the additional resource costs to hospitals of acquiring domestic NIOSH-approved surgical N95 respirators (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we propose to maintain the current adjustment percentage for CY 2023. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2023 are applied uniformly across services,

observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2022 and CY 2023 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2023 would increase Medicare OPPS payments by an estimated 2.9 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 an estimated 3.0 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 84 shows the total number of facilities (3,502), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2021 hospital outpatient and CMHC claims data to model CY 2022 and CY 2023 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 2022 or CY 2023 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,411), 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 25 CMHCs at the bottom of the impact table (Table 84) and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience a 0.1 increase, with the impact ranging from a decrease of 0.3 percent to an increase of 0.6, depending on the number of beds. Rural hospitals will experience an estimated decrease of 0.1 overall. Major teaching hospitals will experience an estimated increase of 0.4 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2023 IPPS post-reclassification wage indexes; the rural adjustment; the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2022 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the proposed CY 2023 changes in wage index policy discussed in section II.C this proposed rule. We did not model a budget neutrality adjustment for the proposed rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2023, as described in section II.E of this proposed rule. We also did not model a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2023 is 0.89, the same as the ratio that was reported for the CY 2022 OPPS/ASC final rule with comment period (85 FR 85914). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are applying in section II.F of this proposed rule.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2023 scaled weights and a CY 2022 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2022 and CY 2023.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 2.7 percent. Overall, these changes will increase payments to urban hospitals by 3.0 percent and to rural hospitals by 2.6 percent. Sole community hospitals receive an estimated increase of 2.5 percent while other rural hospitals receive an estimated increase of 2.6 percent.

Column 5: Off-Campus PBD Clinic Visit Payment Policy

Column 5 displays the estimated effect of including the volume control method to pay for clinic visit HCPCS code G0463 ((Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' by an excepted off-campus PBD at a rate that would continue be 40 percent of the OPPS rate for a clinic visit service for CY 2023. Based on our proposal to apply an exception to this policy for rural sole community hospitals in the CY 2023 OPPS, the column includes estimated increases in payment, which are non-budget neutral.

Column 6: All Changes for CY 2023

Column 6 depicts the full impact of the proposed CY 2023 policies on each hospital group by including the effect of all changes for CY 2023 and comparing them to all estimated payments in CY 2021. Column 6 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G of this proposed rule; the change in the Hospital OQR Program payment reduction for the small number of

hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV of this proposed rule); the proposed change to except rural sole community hospitals from the clinic visit policy when provided at excepted off-campus provider-based departments, and the proposed adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2022 update (and assumed, for modeling purposes, to be the same number for CY 2023), we included 33 hospitals in our model because they had both CY 2021 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2023 will increase payments to all facilities by 2.9 percent for CY 2022. We modeled the independent effect of all changes in Column 6 using the final relative payment weights for CY 2022 and the proposed relative payment weights for CY 2023. We used the proposed conversion factor for CY 2023 of $86.785 and the final CY 2022 conversion factor of $84.177 discussed in section II.B of this proposed rule.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (87 FR 28667) of 6.4 percent (1.06404) to increase charges on the CY 2021 claims, and we used the overall CCR in the April 2022 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2022. Using the CY 2021 claims and a 6.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2022, using a multiple threshold of 1.75 and a fixed-dollar threshold of $6,175, will be approximately 1.29 percent of total payments. The estimated current outlier payments of 1.29 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 13.2 percent (1.13218) and the CCRs in the April 2022 OPSF, with an adjustment of 0.974495 (86 FR 25718), to reflect relative changes in cost and charge inflation between CY 2021 and CY 2023, to model the proposed CY 2023 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $8,350. The charge inflation and CCR inflation factors are discussed in detail in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28666 through 28667).

Overall, we estimate that facilities would experience an increase of 2.9 percent under this proposed rule in CY 2023 relative to total spending in CY 2022. This projected increase (shown in Column 6) of Table 84 of this proposed rule reflects the 2.7 percent OPD fee schedule increase factor, plus 0.34 percent for the change in the pass-through payment estimate between CY 2022 and CY 2023, the proposed change to except rural sole community hospitals from the clinic visit policy when provided at excepted off-campus provider-based departments, and the proposed adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators, minus the difference in estimated outlier payments between CY 2022 (1.29 percent) and CY 2023 (1.0 percent). We estimate that the combined effect of all proposed changes for CY 2023 would increase payments to urban hospitals by 2.9 percent. Overall, we estimate that rural hospitals would experience a 3.2 percent increase as a result of the combined effects of all the proposed changes for CY 2023.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 2.6 percent for major teaching hospitals and an increase of 3.3 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 3.0 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 2.9 percent, proprietary hospitals would experience an increase of 3.5 percent, and governmental hospitals would experience an increase of 2.8 percent.

We note that under our anticipated alternative policy in which 340B-acquired drugs would be paid at ASP+6 percent that providers would experience different estimated changes based on the alternative policy.

Under the anticipated alternative OPPS, the combined effect of all proposed changes for CY 2023 would increase payments to urban hospitals by 4.0 percent. Overall, we estimate that, under the anticipated alternative, rural hospitals would experience a 2.1 percent increase as a result of the combined effects of all the proposed changes for CY 2023.

Among hospitals, by teaching status, under the anticipated alternative, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 5.9 percent for major teaching hospitals and an increase of 2.3 percent for nonteaching hospitals. Under the anticipated alternative, minor teaching hospitals would experience an estimated increase of 3.5 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, under the anticipated alternative, we estimate that voluntary hospitals would experience an increase of 4.0 percent, proprietary hospitals would experience an increase of 0.5 percent, and governmental hospitals would experience an increase of 4.9 percent.

For more information on the changes associated with the anticipated alternative OPPS policy, please see the supporting data files associated with the alternative policy on the CMS website.

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TABLE 84: ESTIMATED IMPACT OF THE CY 2023 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Proposed Rural SCH Exception to Off Campus Provider Based Department Visits Policy	All Changes
ALL PROVIDERS *		3,502	0.0	0.1	2.9	0.1	2.9
ALL HOSPITALS		3,411	0.1	0.2	2.9	0.1	3.0
	(excludes hospitals held harmless and CMHCs)						
URBAN HOSPITALS		2,686	0.1	0.2	3.0	0.0	2.9
	LARGE URBAN	1,376	0.1	0.1	2.9	0.0	2.9
	(GT 1 MILL.)						
	OTHER URBAN	1,310	0.0	0.3	3.0	0.1	3.0
	(LE 1 MILL.)						
RURAL HOSPITALS		725	-0.1	0.0	2.6	0.7	3.2
	SOLE COMMUNITY	374	-0.2	0.1	2.5	1.1	3.4
	OTHER RURAL	351	0.0	-0.1	2.6	0.0	2.7
BEDS (URBAN)							
	0 - 99 BEDS	887	0.6	0.2	3.5	0.0	3.4
	100-199 BEDS	766	0.4	0.2	3.3	0.1	3.3
	200-299 BEDS	415	0.2	0.1	3.0	0.1	3.0
	300-499 BEDS	388	0.1	0.2	3.0	0.0	2.9
	500 + BEDS	230	-0.3	0.2	2.6	0.0	2.6
BEDS (RURAL)							
	0 - 49 BEDS	340	0.1	0.0	2.9	0.2	3.0
	50- 100 BEDS	223	-0.1	0.3	2.9	0.6	3.2
	101- 149 BEDS	85	-0.2	0.1	2.5	0.8	3.2

	150- 199 BEDS	39	-0.2	-0.5	1.9	1.4	3.6
	200 + BEDS	38	-0.3	-0.2	2.2	0.9	3.0
REGION (URBAN)							
	NEW ENGLAND	129	-0.1	0.5	3.1	0.0	3.3
	MIDDLE ATLANTIC	313	-0.1	-0.1	2.4	0.0	2.4
	SOUTH ATLANTIC	449	0.2	0.0	2.9	0.0	3.0
	EAST NORTH CENT.	418	0.0	-0.1	2.6	0.0	2.7
	EAST SOUTH CENT.	159	0.1	-0.2	2.6	0.0	2.7
	WEST NORTH CENT.	178	-0.2	1.2	3.7	0.1	2.9
	WEST SOUTH CENT.	438	0.3	0.0	3.0	0.0	3.1
	MOUNTAIN	200	0.4	0.4	3.5	0.1	3.3
	PACIFIC	354	0.2	0.3	3.3	0.0	3.2
	PUERTO RICO	48	0.3	-0.1	2.8	0.0	3.1
REGION (RURAL)							
	NEW ENGLAND	20	-0.4	-0.5	1.8	1.9	3.6
	MIDDLE ATLANTIC	47	-0.3	-0.5	1.8	1.7	3.9
	SOUTH ATLANTIC	107	0.0	0.2	2.9	0.1	3.3
	EAST NORTH CENT.	118	-0.1	-0.3	2.3	0.3	2.7
	EAST SOUTH CENT.	139	-0.1	-0.3	2.3	0.4	3.0
	WEST NORTH CENT.	88	-0.4	0.7	3.0	1.2	3.2
	WEST SOUTH CENT.	138	0.3	-0.4	2.5	0.6	3.4
	MOUNTAIN	45	0.0	1.7	4.5	0.3	2.9
	PACIFIC	23	-0.3	-0.5	1.9	1.0	3.0
TEACHING STATUS							
	NON-TEACHING	2,200	0.4	0.1	3.2	0.1	3.3
	MINOR	813	0.1	0.1	3.0	0.1	3.0
	MAJOR	398	-0.4	0.3	2.6	0.1	2.6
DSH PATIENT PERCENT							
	0	4	1.1	0.6	4.4	0.0	4.5
	GT 0 - 0.10	242	0.8	0.3	3.8	0.0	3.6
	0.10 - 0.16	211	0.4	0.1	3.3	0.0	3.2

	0.16 - 0.23	565	0.2	0.1	3.1	0.1	3.2
	0.23 - 0.35	1,105	0.0	0.2	2.9	0.2	3.0
	GE 0.35	873	-0.1	0.1	2.7	0.1	2.7
	DSH NOT AVAILABLE **	411	-1.6	0.1	1.2	0.0	0.9
URBAN TEACHING/ DSH							
	TEACHING & DSH	1,074	-0.1	0.2	2.8	0.0	2.8
	NO TEACHING/DSH	1,215	0.5	0.1	3.3	0.0	3.3
	NO TEACHING/NO DSH	4	1.1	0.6	4.4	0.0	4.5
	DSH NOT AVAILABLE2	393	-1.6	0.1	1.1	0.0	0.9
TYPE OF OWNERSHIP							
	VOLUNTARY	1,940	0.0	0.1	2.8	0.1	2.9
	PROPRIETARY	1,033	0.7	0.0	3.5	0.0	3.5
	GOVERNMENT	438	-0.2	0.3	2.8	0.1	2.8
CMHCs		25	-11.3	0.2	-8.7	0	-8.4

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2023 OPPS policies and compares those to the CY 2022 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2023 hospital inpatient wage index. The proposed rural SCH adjustment would continue 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 1.0000 because the proposed CY 2023 target payment-to-cost ratio is the same as the CY 2022 PCR target (0.89)

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.7 percent OPD fee schedule update factor (3.1 percent reduced by 0.4 percentage points for the productivity adjustment).

Column (5) shows the differential impact of the proposed exception for rural sole community hospitals from clinic visits policy when furnished at off campus provider based departments.

Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.

These 3,502 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.

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e. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 84 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2022, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2021 claims used for ratesetting in the 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 8.4 percent decrease in payments from CY 2022 (shown in Column 6). We note that this includes the trimming methodology as well as the proposed CY 2023 geometric mean costs used for developing the PHP payment rates described in section VIII. of this proposed rule.

Column 3 shows the estimated impact of adopting the proposed FY 2023 wage index values would result in an increase of 0.2 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2023 and the proposed FY 2023 wage index updates, will result in an estimated decrease of 8.7 percent. Column 6 shows that adding the changes in outlier and pass-through payments would result in a total −8.4 percent decrease in payment for CMHCs. This reflects all proposed changes for CMHCs for CY 2023.

f. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would 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 of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H 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 17.8 percent for all services paid under the OPPS in CY 2023. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2023 comprehensive APC payment policy discussed in section II.A.2.b of this proposed rule. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

g. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the changes in this proposed rule.

h. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $1.8 billion in program payments for OPPS services furnished in CY 2023. 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 estimate that the changes in this proposed rule would increase these Medicaid beneficiary payments by approximately $115 million in CY 2023. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately thirty percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 30 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated $115 million Medicaid increase, approximately $65 million would be from the Federal Government and $50 million would be from State governments.

i. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we propose and the reasons for our selected alternatives are discussed throughout this proposed rule.

- Alternatives Considered for the Claims Data used in OPPS and ASC Ratesetting due to the PHE.

We refer readers to section X.B of this proposed rule for a discussion of our proposed policy of using cost report data prior to the PHE. We note that in that section we discuss the alternative proposal we are considering regarding applying the standard ratesetting process, in particular the selection of cost report data used, which would include claims and cost report data including the timeframe of the PHE. We note that there are potential issues related to that data, including the effect of the PHE on the provider departmental CCRs that would be used to estimate cost. In this proposed rule, as discussed in section X.D, we propose a policy of using updated CY 2021 claims data in CY 2023 OPPS ratesetting, while using cost report CCRs with reporting periods prior to the PHE.

We note that these policy considerations also have ASC implications since the relative weights for certain surgical procedures performed in the ASC setting are developed based on the OPPS relative weights and claims data.

- Alternative Considered for the Proposed Adjustment for Acquisition of Domestic NIOSH-approved Surgical N95 Respirators.

We refer readers to section X.H of this proposed rule for a discussion of our proposed IPPS and OPPS payment adjustments for the additional resource costs that hospitals incur in procuring domestic NIOSH-approved surgical N95 respirators. We note that in that section we discuss an alternative proposal of basing the payment adjustments on the national average cost differential between a domestic NIOSH-approved surgical N95 respirator and a non-domestic one as collected on the hospital cost reports, rather than using hospital specific differentials. We state that we may consider this alternative proposal once we've gained more experience with this payment policy, if finalized, its impact on the N95 marketplace, and the data collected. As discussed later in this section, our best estimate of the difference in the average unit costs of domestic and non-domestic NIOSH-approved surgical N95 respirators is $0.20. Using this figure, we estimate the impact of this alternative policy would be the same as the policy we propose in section X.H of this proposed rule. Our estimates of the CY 2023 IPPS and OPPS payment associated with our proposed policy are $3.1 million and $8.3 million, respectively, and are discussed in more detail in this section.

2. Estimated Effects of CY 2023 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII of this proposed rule, we are setting the CY 2023 ASC relative payment weights by scaling the proposed CY 2023 OPPS relative payment weights by the proposed ASC scalar of 0.8474. 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 85 and 86.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket update for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. Section 1886(b)(3)(B)(xi)(II) of the 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 (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 2023 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which would be the hospital market basket update for CY 2023. We calculated the CY 2023 ASC conversion factor by adjusting the CY 2022 ASC conversion factor by 1.0010 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2022 and CY 2023 and by applying the CY 2023 productivity-adjusted hospital market basket update factor of 2.7 percent (which is equal to the projected hospital market basket update of 3.1 percent reduced by a productivity adjustment of 0.4 percentage point). The CY 2023 ASC conversion factor is $51.315 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2023 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2021 and CY 2023 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2023 changes would 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 would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2023 payments would 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 includes tables that display estimates of the impact of the proposed CY 2023 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2021 claims data. Table 85 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2022 payments to estimated CY 2023 payments, and Table 86 shows a comparison of estimated CY 2022 payments to estimated CY 2023 payments for procedures that we estimate would receive the most Medicare payment in CY 2022.

In Table 85, 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 85.

- 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 2022 ASC Payments were calculated using CY 2021 ASC utilization data (the most recent full year of ASC utilization) and CY 2022 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2022 ASC payments.
- Column 3—Estimated CY 2023 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 is attributable to proposed updates to ASC payment rates for CY 2023 compared to CY 2022.

As shown in Table 85, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2023 would result in a 1 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 4 percent increase in aggregate payment amounts for nervous system procedures, 6 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 2 percent increase in aggregate payment amounts for digestive system procedures, a 1 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 3 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.7 percent proposed payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.0 percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 6 percent increase in proposed aggregate musculoskeletal procedure payments. The increase in payment

rates for musculoskeletal procedures as a result of increased device portions is further increased by the proposed 2.7 percent ASC rate update for these procedures. Conversely, we estimate only a 1 percent increase in proposed aggregate eye and ocular adnexa procedures related to a decrease in OPPS relative weights partially offsetting the 2.7 percent ASC rate update. For estimated changes for selected procedures, we refer readers to Table 85 provided later in this section.

TABLE 85: ESTIMATED IMPACT OF THE CY 2023 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2022 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2022 ASC Payments (in Millions) (2)	Estimated CY 2023 Percent Change (3)
Total	$5,858	3
Eye	$1,789	1
Nervous System	$1,200	4
Musculoskeletal	$999	6
Gastrointestinal	$896	2
Cardiovascular	$262	1
Genitourinary	$215	3

Table 85 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2023. The table displays 30 of the procedures receiving the greatest estimated CY 2022 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2022 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2022 ASC Payments were calculated using CY 2021 ASC utilization (the most recent full year of ASC utilization) and the CY 2022 ASC payment rates. The estimated CY 2022 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2023 Percent Change reflects the percent differences between the estimated ASC payment for CY 2022 and the estimated payment for CY 2023 based on the proposed update.

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TABLE 86 : ESTIMATED IMPACT OF THE FINAL CY 2023 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2022 ASC Payment (in millions) (3)	Estimated CY 2023 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,196	2
63685	Insrt/redo spine n generator	$300	3
45380	Colonoscopy and biopsy	$235	3
45385	Colonoscopy w/lesion removal	$191	3
27447	Total knee arthroplasty	$182	4
63650	Implant neuroelectrodes	$174	9
43239	Egd biopsy single/multiple	$160	1
64483	Njx aa&/strd tfrm epi l/s 1	$106	2
66991	Xcapsl ctrc rmvl insj 1+	$98	0
64590	Insrt/redo pn/gastr stimul	$95	7
66982	Xcapsl ctrc rmvl cplx wo ecp	$91	2
27130	Total hip arthroplasty	$81	6
64635	Destroy lumb/sac facet jnt	$77	1
29827	Sho arthrs srg rt8tr cuf rpr	$72	2
J1097	Phenylep ketorolac opth soln	$71	-4
64493	Inj paravert f jnt l/s 1 lev	$66	2
36902	Intro cath dialysis circuit	$65	3
G0105	Colorectal scrn; hi risk ind	$60	3
66821	After cataract laser surgery	$60	4
C9740	Cysto impl 4 or more	$51	1
62323	Njx interlaminar lmbr/sac	$45	0
22869	Insj stablj dev w/o dcmprn	$43	6
27279	Arthrodesis sacroiliac joint	$42	28
45378	Diagnostic colonoscopy	$37	3
G0121	Colon ca scrn not hi rsk ind	$36	3
64561	Implant neuroelectrodes	$35	7
15823	Revision of upper eyelid	$35	-1
64721	Carpal tunnel surgery	$34	1
65820	Relieve inner eye pressure	$32	1
J1096	Dexametha opth insert 0.1 mg	$32	0

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c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2023 update to the ASC payment system would be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures proposed to be designated as office-based for CY 2023. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense based amount payable under the PFS. For those additional procedures that we proposed to designate as office-based in CY 2023, the beneficiary coinsurance amount under the ASC payment system

generally will be no greater than the beneficiary coinsurance under the PFS 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).

3. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html*), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 87, illustrates the classification of expenditures for the CY 2023 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2023 OPD fee schedule increase. The second accounting statement, Table 88, illustrates the classification of expenditures associated with the proposed 2.7 percent CY 2023 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. Table 89 includes the annual estimated impact of hospital OQR and ASCQR programs, and the prior authorization process.

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TABLE 87: ACCOUNTING STATEMENT: CY 2023 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2022 TO CY 2023 ASSOCIATED WITH THE CY 2023 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1,790 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 88: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2022 TO CY 2023 AS A RESULT OF THE PROPOSED CY 2023 UPDATED TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$110 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$110 million

TABLE 89: ESTIMATED COSTS IN CY 2023

CATEGORY	Costs
Burden	$-11,688,943 million*
Regulatory Familiarization	$17.204 million**

*The annual estimate includes the impact of Hospital OQR and ASCQR Programs, and the Prior Authorization Process.

** Regulatory familiarization costs occur upfront only.

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4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59492 through 59494) for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting (OQR) Program for the CY 2018, CY 2019, and CY 2021 payment determinations. Of the 3,356 hospitals that met eligibility requirements for the CY 2022 payment determination, we determined that 88 hospitals did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor.

b. Impact of CY 2023 OPPS/ASC Proposed Rule Policies

We do not anticipate that the CY 2023 Hospital OQR Program proposed policies will impact the number of facilities that will receive payment reductions. In this proposed rule, we propose to—(1) add an additional targeting criterion to the validation selection policy beginning with the CY 2023 reporting period; (2) align the patient encounter quarters with the calendar year beginning with the CY 2024 reporting period; and (3) change reporting for the OP–31 measure from mandatory to voluntary beginning with the CY 2025 payment determination.

As shown in Table 81 in section XXIII.B.4 (Collection of Information) of this proposed rule, we estimate a total information collection burden decrease for 3,350 OPPS hospitals of −325,847

hours at a cost of −$15,138,852 annually associated with our proposed policies and updated burden estimates for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, compared to our currently approved information collection burden estimates. We refer readers to section XXIII.B of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital OQR Program. We do not believe the proposed policies will have any further economic impact beyond information collection burden.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XV of this proposed rule, we discuss our proposed policies affecting the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. For the CY 2022 payment determination, of the 5,386 ASCs that met eligibility requirements, we determined that 290 ASCs did not meet the requirements to receive the full annual payment update under the ASC fee schedule.

b. Impact of CY 2023 OPPS/ASC Proposed Policies

In section XVI of this proposed rule, we propose to change reporting for the ASC–11 measure from mandatory to voluntary beginning with the CY 2023 reporting period. As shown in Table 82 in section XXIII.C.3.e (Collection of Information), we estimate a total information collection burden decrease for 4,646 ACSs of −72,107 hours at a cost of −$3,350,091 annually associated with our proposed policies and updated burden estimates for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, compared to our currently approved information collection burden estimates. We refer readers to section XXIII.C of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the ASCQR Program. We do not believe the proposed policy will have any further economic impact beyond information collection burden.

6. Effects of Requirements for the Rural Emergency Hospitals (REH) Program

a. Background

In section XVIII.A of this proposed rule, we discuss our proposed policies to provide payment to REHs, including the following proposals: (1) the payment rate for an REH service would be calculated using the OPPS prospective payment rate for the equivalent covered OPD service increased by 5 percent; (2) the additional 5 percent payment for REH services, above the amount that would be paid for covered OPD services, would not be subject to a copayment; (3) For CY 2023, the monthly facility payment that each REH will receive would be determined by first calculating the total amount that CMS determines was paid to all CAHs under Title 18 of the Act in CY 2019 minus the estimated total amount that would have been paid under Title 18 to CAHs in CY 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during CY 2019. The difference is divided by the number of CAHs enrolled in Medicare in CY 2019 to calculate the annual amount of this additional facility payment per individual REH. The annual payment amount is then divided by 12 to calculate the monthly facility payment that each REH will receive.

b. Impact of CY 2023 OPPS/ASC Proposed Rule REH Policies

For CY 2023, we have determined there are 1,716 CAHs and rural subsection (d) hospitals with 50 or fewer beds that are eligible to convert to become an REH in the nation. A study [360] estimated that 68 eligible providers or approximately 4 percent of all eligible providers would become a REH in CY 2023, and we use this number of REHs for our impact analyses. We acknowledge that the number of conversions could be less than or significantly greater than this estimate.

We developed a percentile analysis estimating how much revenue from rendering medical services a provider would lose or gain during CY 2023 if it decided to convert to a REH. We estimated that a provider in the 95th percentile of total annual REH medical service payment would receive an additional $2,089,700 in Medicare payments. We estimated that a provider in the 100th percentile of total annual REH medical service payment would receive an additional $3,362,560 in Medicare payments. Since a REH provider conversion rate of 4 percent falls between the 95th percentile and the 100th percentile of total annual REH medical service payment spending, we took the average of the additional spending for the 95th and 100th percentiles to determine the additional medical service spending for each provider converting to a REH in CY 2023 would be $2,726,130. Since we do not have any information on individual providers that may convert, nor do we have any information on characteristics of regions where REH conversions may be more likely, our best assumption regarding the impact of the REH policy is that providers who anticipate the most financial benefit from converting to an REH would be the most likely providers to convert.

Next, we determined the annual facility payment amount for a provider that converts to an REH in CY 2023. The proposed monthly facility payment for CY 2023 is $268,294. When this amount is multiplied by 12 months, the total annual facility payment is equal to $3,219,524. To determine the total impacts of the REH policy, we need to multiply the additional medical service spending amount of $2,726,130 by 68 providers which equals $185,376,820. Next, we multiply the total annual facility payment amount of $3,219,524 by 68 providers which equals $218,927,610. Finally, we combine the two amounts together, and we obtain a final estimate of the impacts of the REH provider policy of an additional $404,304,430 in Medicare payments.

7. Effects of Rural Emergency Hospitals (REH) Physician Self-Referral Law Updates

The physician self-referral law provisions related to REHs are discussed in section XVII.E. of this proposed rule.

As discussed in section XVIII.E.3 of this proposed rule, we propose a new exception at § 411.356(c)(4) for ownership or investment interests held by physicians (or immediate family members of physicians) in an REH. If all the requirements of the proposed exception are satisfied, the physician's (or immediate family member's) ownership or investment interest in the REH would not constitute a financial relationship for purposes of the physician self-referral law, and the referral and billing prohibitions of the physician self-referral law would not apply.

All the hospitals that are eligible to convert to an REH are either critical access hospitals or small rural hospitals and, therefore, are currently considered ''hospitals'' for purposes of the physician self-referral law. We believe that most physician-owned entities that are not publicly traded currently rely on

[360] ''How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?'' July 2021. Pink, GH et al. *Findings Brief—NC Rural Health Research Program.*

the rural provider and whole hospital exceptions in our regulations at § 411.356(c)(1) and (3), respectively. The proposed REH exception includes program integrity requirements similar to those under the rural provider and whole hospital exceptions. Thus, we anticipate that the requirements of the proposed REH exception would result in no additional burden to a physician-owned REH and would protect against program or patient abuse. We believe that the proposed REH exception would ensure that the physician self-referral law does not inhibit access to medically necessary designated health services furnished by REHs that are owned or invested in by physicians (or their immediate family members) or thwart the underlying goal of section 125 of the CAA to safeguard or expand such access.

As discussed in section XVIII.E.5 of this proposed rule, we also propose to revise certain existing exceptions applicable to compensation arrangements involving specific types of providers to make them applicable to compensation arrangements to which an REH is a party. Specifically, we propose to revise the exceptions for physician recruitment at § 411.357(e), obstetrical malpractice insurance subsidies at § 411.357(r), retention payments in underserved areas at § 411.357(t), electronic prescribing items and services at § 411.357(v), assistance to compensate a nonphysician practitioner at § 411.357(x), and timeshare arrangements at § 411.357(y) to also permit an REH to provide remuneration to a physician (or an immediate family member of a physician) if all requirements of the applicable exception are satisfied. All the proposed revisions would ensure that exceptions that may already be used by existing CAHs and small rural hospitals eligible to undergo conversion to an REH remain available to REHs. We believe that the continued availability of these exceptions could be important to ensuring access to necessary designated health services and other care furnished by an REH.

8. REH Enrollment

The only impacts of our proposed REH enrollment policies are the information collection requirements associated with the facility's completion and submission of a Form CMS–855A change of information application to convert from a CAH or hospital (as defined in section 1886(d)(1)(B) of the Act) to an REH. These are addressed in detail in section XXIII.G of this proposed rule. As explained in that section, we estimate a Year 1 burden of 68 hours (68 applications × 1 hour per application) at a cost of $2,784 (based on an hourly wage estimate of $40.94). Over a 3-year period, this results in an annual burden of 23 hours at a cost of $928.

9. Effects of Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142, November 12, 2019).[361] As part of the CY 2021 OPPS/ASC final rule (CMS–1736–FC), we added additional service categories to the prior authorization process (85 FR 85866, December 29, 2020). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to require prior authorization for a new service category: Facet Joint Interventions. We propose adding the service category to § 419.83(a)(3). We also propose that the prior authorization process for the additional service category would be effective for dates of services on or after March 1, 2023. The addition of the service category is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the health care sector to require prior authorization for the additional service category is dependent on the number of claims affected. Table 90, Overall Economic Impact on the Health Sector, lists an estimate of the overall economic impact on the health sector for the new service category. The values populating this table were obtained from the cost reflected in Table 91, Annual Private Sector Costs, and Table 92, Estimated Annual Administrative Costs to CMS. Together, Tables 91 and 92 combine to convey the overall economic cost impact to the health sector for the new service category, which is illustrated in Table 90. It should be noted that due to the March start date for prior authorization for the new service category, year one includes only 10 months of prior authorization requests.

Based on the estimate, the overall economic cost impact would be approximately $22 million in the first year based on 10 months for the new service category. The 5-year impact would be approximately $127.4 million, and the 10-year impact would be approximately $259.2 million. The 5- and 10-year impacts account for year one, including only 10 months. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of $65.3 million. We believe there are likely to be other benefits that would result from the prior authorization requirement for the new service category, though many of those benefits are difficult to quantify. For instance, we would expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We are soliciting public comments on the potential increased costs and benefits associated with this proposed provision for the new service category.

[361] See also Correction Notice issued January 3, 2020 (85 FR 224).

TABLE 90: OVERALL ECONOMIC COST IMPACT ON THE HEALTH SECTOR

	Year 1	5 Years	10 Years
Private Sector Costs	$5,987,841	$34,524,944	$70,196,322
Medicare Costs	$16,018,431	$92,881,139	$188,959,524
Total Economic Impact to Health Sector	$22,006,272	$127,406,083	$259,155,846

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of $10 million or less in any 1 year. While the economic costs and benefits are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations would be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant, as the proposed rule would change the billing practices of those providers. We believe that the purpose of the statute and this rule is to avoid unnecessary increases in utilization of OPD services. Therefore, we do not view decreased revenues from the additional OPD service category subject to unnecessary utilization by providers to be a condition that we must mitigate. We believe that the effect would be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. Adding the new service category would offer additional protection to a provider's cash flow as the provider would know in advance if the Medicare requirements are met.

b. Anticipated Specific Cost Effects

1. Private Sector Costs

We do not believe that this rule would significantly affect the number of legitimate claims submitted for the new service category. However, we would expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the additional service category would be equivalent to that of submitting documentation and clerical activities associated with prepayment review, which is 0.5 hours. We would apply this time burden estimate to initial submissions and resubmissions.

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TABLE 91: YEAR 1 (10 MONTH) PRIVATE SECTOR COSTS

Activity	Responses Per Year (i.e., number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests-Initial Submissions	162,169	0.5	81,085	$2,777,955
Fax and Electronic Submitted Requests-Resubmissions	53,213	0.5	26,606	$911,532
Mailed in Requests-Initial Submissions	69,501	0.5	34,751	$1,190,552
Mailed in Requests-Resubmissions	22,805	0.5	11,403	$390,657
Mailing Costs	92,306	5		$461,532
Provider Demonstration-Education	2,487	3	7,461	$255,614
Total			161,305	$5,987,841

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2. Administrative Costs to CMS

CMS would incur additional costs associated with processing the prior authorization requests for the new service category. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $50, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education, outreach, and system changes.

TABLE 92: YEAR 1 (10 MONTH) ESTIMATED ADMINISTRATIVE COSTS TO CMS

Service Category	Estimated Year One Administrative Cost (10 Months)
Facet Joint Interventions- 10 Codes	$16,018,431

3. Estimated Beneficiary Costs

We would expect a reduction in the utilization of the new Medicare OPD service category when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision; we are unable to quantify that burden. Although the rule would permit utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

c. Estimated Benefits

There would be quantifiable benefits for this rule because we expect a reduction in the unnecessary utilization of the new Medicare OPD service category subject to prior authorization. It is difficult to project the exact decrease in unnecessary utilization; however, based on a 25 percent savings percentage, we estimate that for the first ten months, there would be savings of $54.4 million overall. Annually, we estimate an overall gross savings of $65.3 million. This savings represents a Medicare benefit from more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We would closely monitor utilization and billing practices. The expected benefits would also include changed billing practices

that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the additional OPD services category would ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine what services are medically necessary based on the beneficiary's condition. This would require the facility to collaborate closely with the practitioner early on in the process to ensure the services are truly necessary and meet all requirements and that their supporting documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient or the patient does not meet the Medicare requirements would likely be reduced by the requirement that a provider submits clinical documentation created as part of its prior authorization request.

D. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a 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 a rule, we assumed that the number of commenters on last year's proposed rule (18,664) 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 choose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach to estimating the number of entities that will review the proposed rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this proposed rule. For each facility that reviewed the proposed rule, the estimated cost is $921.76 (8 hours × $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $17,203,729 ($921.76 × 18,664).

E. 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, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 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 $16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards*. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. As a result, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small entities.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period would increase payments to small rural hospitals by approximately 3 percent. Therefore, it should not have a significant impact on the approximately 563 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis. We note that the policies established in this proposed rule apply more broadly to OPPS providers and do not specifically focus on small rural hospitals. As a result, the impact on those providers may depend more significantly on their case mix of services provided, since the broader impact on the hospital category is more dependent on the OPD update factor, as indicated in the impact table.

F. 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. In 2022, that threshold level is currently approximately $165 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

G. Conclusion

The changes we propose in this proposed rule would affect all classes of hospitals paid under the OPPS as well as 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 2023. Table 84 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 2.9 percent increase in payments for all services paid under the OPPS in CY 2023, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, changes to the pass-through payment estimate, proposed exception for rural SCHs from the clinic visit policy for services furnished at off campus PBDs, and proposed adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2023.

The updates we are making to the ASC payment system for CY 2023 would affect each of the approximately 5,900 ASCs currently approved for participation in the Medicare program.

The effect on an individual ASC would depend on its mix of patients, the proportion of the ASCs 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 than in previous years. Table 85 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.7 percent for CY 2023.

H. 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 84 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.8 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. However, as noted in section XXV, this proposed rule should not have a significant effect on small rural hospitals.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 6, 2022.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.1801 is amended by revising paragraph (b)(2)(ii) to read as follows:

§ 405.1801 Introduction.

* * * * *

(b) * * *

(2) * * *

(ii) Some of these nonprovider entities are required to file periodic cost reports and are paid on the basis of information furnished in these reports. Except as provided at § 413.420(g), these nonprovider entities may not obtain a contractor hearing or a Board hearing under section 1878 of the Act or this subpart.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 3. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 4. Section 410.27 is amended by:

■ a. Revising paragraphs (a)(1)(iv)(A) and (B); and

■ b. Removing paragraph (a)(1)(iv)(D).

The revisions read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this chapter, general supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure.

(B) Certain therapeutic services and supplies may be assigned either direct supervision or personal supervision.

(*1*) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2021, the presence of the physician includes virtual presence through audio/video real-time communications technology (excluding audio-only);

(*2*) Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure;

* * * * *

■ 5. Section 410.28 is amended by revising paragraph (e) to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished by or under arrangements made by the participating hospital only when the diagnostic services are furnished under one of the three levels of supervision (as defined in paragraphs (e)(1) through (3) of this section) specified by CMS for the particular service by a physician or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nonphysician practitioner (physician assistant, nurse practitioner, clinical nurse specialist, certified nurse-midwife or certified registered nurse anesthetist).

(1) *General supervision.* General supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure. Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

(2) *Direct supervision.* (i) For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65 of this chapter, ''direct supervision'' means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room where the procedure is performed.

(ii) For services furnished under arrangement in nonhospital locations, ''direct supervision'' means the physician or nonphysician practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.

(iii) Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2021, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).

(3) *Personal supervision.* Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure.

* * * * *

■ 6. Section § 410.40 is amended by revising paragraphs (f)(1), (2), and (5) to read as follows:

§ 410.40 Coverage of ambulance services.

* * * * *

(f) * * *

(1) From any point of origin to the nearest hospital, CAH, REH, or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH or REH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, REH, or SNF to the beneficiary's home.

* * * * *

(5) During a Public Health Emergency, as defined in § 400.200 of this chapter, a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with any applicable State or local Emergency Medical Services protocol that governs the destination location. Such destinations include, but are not limited to, alternative sites determined to be part of a hospital, critical access hospital, REH (effective January 1, 2023), or skilled nursing facility, community mental health centers, federally qualified health centers, rural health clinics, physician offices, urgent care facilities, ambulatory surgical centers, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 7. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 8. Section 411.351 is amended by revising the definition of ''Rural area'' and adding a definition for ''Rural emergency hospital'' to read as follows:

§ 411.351 Definitions.

* * * * *

Rural area means an area that is not an urban area as defined at § 412.64(b) of this chapter.

Rural emergency hospital has the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91 of this chapter.

* * * * *

■ 9. Section 411.356 is amended by adding paragraph (c)(4) to read as follows:

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

* * * * *

(c) * * *

(4) A rural emergency hospital, in the case of designated health services that are furnished by such rural emergency hospital, if all of the following requirements are satisfied:

(i) The entity is enrolled in Medicare as a rural emergency hospital.

(ii) The ownership or investment interest is in the entire rural emergency hospital and not merely in a distinct part or department of the rural emergency hospital.

(iii) The rural emergency hospital does not directly or indirectly condition any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the rural emergency hospital or otherwise generating business for the rural emergency hospital.

(iv) The rural emergency hospital does not offer any ownership or investment interests to a physician (or an immediate family member of a physician) on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician).

(v) Neither the rural emergency hospital nor any owner of or investor in the rural emergency hospital directly or indirectly provides loans or financing for any investment in the rural emergency hospital by a physician (or an immediate family member of a physician).

(vi) Neither the rural emergency hospital nor any owner of or investor in the rural emergency hospital directly or indirectly guarantees a loan, makes a payment toward a loan, or otherwise subsidizes a loan for a physician (or an immediate family member of a

physician) that is related to acquiring any ownership or investment interest in the rural emergency hospital.

(vii) Ownership or investment returns are distributed to each owner of or investor in the rural emergency hospital in an amount that is directly proportional to the ownership or investment interest in the rural emergency hospital of such owner or investor.

(viii) Physicians (or immediate family members of physicians) who have ownership or investment interests in the rural emergency hospital do not directly or indirectly receive any guaranteed receipt of or right to purchase other business interests related to the rural emergency hospital, including the purchase or lease of any property under the control of any other owner of or investor in the rural emergency hospital or located near the premises of the rural emergency hospital.

(ix) The rural emergency hospital does not offer a physician (or an immediate family member of a physician) the opportunity to purchase or lease any property under the control of the rural emergency hospital or any other owner of or investor in the rural emergency hospital on more favorable terms than the terms offered to a person that is not a physician (or an immediate family member of a physician).

■ 10. Section 411.357 is amended by revising paragraphs (e)(6), (r)(2) introductory text, (r)(2)(ii) through (v), (t)(5), (v)(1)(i), (x)(7), and (x)(8) and adding paragraph (y)(10) to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(e) * * *

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center, rural health clinic, or rural emergency hospital is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center, rural health clinic, or rural emergency hospital may include one or more zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients.

* * * * *

(r) * * *

(2) A payment from a hospital, federally qualified health center, rural health clinic, or rural emergency hospital that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

* * * * *

(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment, and specifies the payment to be made by the hospital, federally qualified health center, rural health clinic, or rural emergency hospital and the terms under which the payment is to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment.

(iv) The hospital, federally qualified health center, rural health clinic, or rural emergency hospital does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), rural health clinic(s), or rural emergency hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(t) * * *

(5) *Application to other entities.* This paragraph (t) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital. For purposes of paragraph (t), the geographic area served by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in section (e)(6)(ii) of this section.

* * * * *

(v) * * *

(1) * * *

(i) Hospital or rural emergency hospital to a physician who is a member of its medical staff;

* * * * *

(x) * * *

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) * * *

(10) This paragraph (y) applies to remuneration provided by a rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 11. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 12. Section 412.1 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(1) * * *

(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, and for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators.

* * * * *

■ 13. Section 412.2 is amended by adding paragraph (f)(10) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(f) * * *

(10) A payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as specified in § 412.113 of subpart H.

* * * * *

■ 14. Section 412.100 is amended by revising paragraph (b) to read as follows:

§ 412.100 Special treatment: Kidney transplant programs.

* * * * *

(b) *Costs of kidney acquisition.* Kidney acquisition costs include allowable costs incurred in the acquisition of a kidney from a living or a deceased donor by the hospital, or from a deceased donor by an organ procurement organization. These costs are listed in § 413.402(b) of this chapter.

■ 15. Section 412.113 is amended by adding paragraph (f) to read as follows:

§ 412.113 Other payments.

* * * * *

(f) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators.* (1) For cost reporting periods beginning on or after January 1, 2023, a payment adjustment to a hospital for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators is made as described in paragraph (f)(2) of this section.

(2) The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period as compared to other National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period.

■ 16. Section 412.190 is amended by revising paragraph (c) to read as follows:

§ 412.190 Overall Hospital Quality Star Rating.

* * * * *

(c) *Frequency of publication and data used.* The Overall Star Rating are published once annually using data publicly reported on Hospital Compare or its successor website from a quarter within the previous 12 months.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 17. The authority citation for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 18. Section 413.1 is amended by adding paragraph (a)(1)(ii)(L) and revising paragraph (a)(2)(i) to read as follows:

§ 413.1 Introduction.

(a) * * *

(1) * * *

(ii) * * *

(L) Section 1834(x) of the Act authorizes payment for services furnished by Rural Emergency Hospitals (REHs) and establishes the payment methodology.

(2) * * *

(i) Hospitals, critical access hospitals (CAHs), and rural emergency hospitals (REHs);

* * * * *

■ 19. Section 413.13 is amended by adding paragraph (c)(2)(vii) to read as follows:

§ 413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.

* * * * *

(c) * * *

(2) * * *

(vii) *Services furnished by a rural emergency hospital (REH).* Services furnished by a rural emergency hospital are subject to the payment methodology set forth in part 419, subpart K.

* * * * *

■ 20. Section 413.24 is amended by revising paragraphs (f)(4)(i) and (ii) and (f)(4)(iv)(A) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(4) * * *

(i) As used in this paragraph, ''provider'' means a hospital, rural emergency hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, histocompatibility laboratory, rural health clinic, federally qualified health center, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989 for hospitals; cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies; cost reporting periods ending on or after December 31, 2004 for hospices, and end-stage renal disease facilities; cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers; and cost reporting periods beginning on or after January 1, 2023 for rural emergency hospitals, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the contractor's automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the contractor for processing through its system.

* * * * *

(iv)(A) Effective as specified in paragraphs (f)(4)(iv)(A)(*1*) through (*5*) and except as provided in paragraph (f)(4)(iv)(C) of this section, a provider must submit a hard copy of a settlement summary, if applicable, which is a statement of certain worksheet totals found within the electronic file, and the certification statement described in paragraph (f)(4)(iv)(B) of this section signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report.

(*1*) For hospitals, effective for cost reporting periods ending on or after September 30, 1994;

(*2*) For skilled nursing facilities and home health agencies, effective for cost reporting periods ending on or after February 1, 1997;

(*3*) For hospices and end-stage renal disease facilities, effective for cost reporting periods ending on or after December 31, 2004;

(*4*) For organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, effective for cost reporting periods ending on or after March 31, 2005; and

(*5*) For rural emergency hospitals, effective for cost reporting periods beginning on or after January 1, 2023.

* * * * *

■ 21. Section 413.198 is amended by revising paragraph (b)(4)(ii) to read as follows:

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

* * * * *

(b) * * *

(4) * * *

(ii) Section 413.420, Payment to independent organ procurement organizations and to histocompatibility laboratories for kidney acquisition costs;

* * * * *

■ 22. Section 413.400 is amended by revising the definitions of ''Hospital-based organ procurement organization (HOPO)'', ''Transplant hospital'', ''Transplant hospital/HOPO (TH/HOPO)'', and ''Transplant program'' to read as follows:

§ 413.400 Definitions.

* * * * *

Hospital-based organ procurement organization (HOPO) means an organ procurement organization that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report.

* * * * *

Transplant hospital (*TH*) means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant hospital/HOPO (*TH/HOPO*) refers to a TH, or a TH that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the TH's Medicare cost report.

Transplant program means an organ-specific transplant program within a TH (as defined in this section).

* * * * *

■ 23. Section 413.402 is amended by revising paragraphs (a), (b)(3), (4), and (7), (b)(8)(i) and (ii), and (d)(2)(ii) to read as follows:

§ 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are allowable costs incurred in the acquisition of organs from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH/HOPO.

(b) * * *

(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or deceased donor.

(4) Operating room and other inpatient ancillary services applicable to the living or deceased donor.

* * * * *

(7) Surgeons' fees for excising deceased organs (currently limited to $1,250 for kidneys).

(8) * * *

(i) Excised organ to the TH; and

(ii) Deceased donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.

* * * * *

(d) * * *

(2) * * *

(ii) Transportation costs of the deceased donor after organ procurement for funeral services or for burial.

* * * * *

■ 24. Section 413.404 is amended by revising paragraphs (a)(2), (b)(2), (b)(3) introductory text, (b)(3)(i) introductory text, (b)(3)(i)(A) through (C), (b)(3)(ii) introductory text, (b)(3)(ii)(A) and (B), (b)(3)(ii)(C) introductory text, (b)(3)(ii)(C)(*1*) through (*3*), (c)(1)(i) and (ii), (c)(2)(i) through (iv), and (c)(3) to read as follows:

§ 413.404 Standard acquisition charge.

(a) * * *

(2) The SAC represents the average of the total organ acquisition costs associated with procuring either deceased donor organs or living donor organs, by organ type.

* * * * *

(b) * * *

(2) When a TH/HOPO furnishes an organ to another TH or IOPO, it must bill the receiving TH or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

(3) A TH must establish SACs for living donor organs. A TH/HOPO must establish SACs for deceased donor organs.

(i) Living donor SAC for THs—

(A) *Definition.* The living donor SAC is an average organ acquisition cost that a TH incurs to procure an organ from a living donor.

(B) *Establishment of living donor SAC.* A TH must establish a living donor SAC before the TH bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC*—(*1*) *Initial living donor SAC.* A TH calculates its initial living donor SAC for each living donor organ type as follows:

(*i*) By estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period.

(*ii*) By dividing the estimated amount described in paragraph (b)(3)(i)(C)(*1*)(*i*) of this section by the projected number of usable living donor organs to be procured by the TH during the TH's cost reporting period.

(*2*) *Subsequent living donor SAC.* A TH calculates its subsequent years' living donor SAC for each living donor organ type as follows:

(*i*) By using the TH's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) Dividing the costs in paragraph (b)(3)(i)(C)(*2*)(*i*) of this section by the actual number of usable living donor organs procured by the TH during that prior cost reporting period.

* * * * *

(ii) *Deceased donor SAC for TH/HOPOs*—(A) *Definition.* The deceased donor SAC is an average cost that a TH/HOPO incurs to procure a deceased donor organ.

(B) *Calculating the deceased donor SAC*—(*1*) *Initial deceased donor SAC.* A TH/HOPO calculates its initial deceased donor SAC for each deceased donor organ type as follows:

(*i*) By estimating the reasonable and necessary costs it expects to incur to procure deceased donor organs, combined with the expected costs of acquiring deceased donor organs from OPOs or other THs.

(*ii*) By dividing the estimated amount described in paragraph (b)(3)(ii)(B)(*1*)(*i*) of this section by the projected number of usable deceased donor organs to be procured by the TH/HOPO within the TH's cost reporting period.

(*2*) *Subsequent deceased donor SAC.* A TH/HOPO calculates its subsequent years' deceased donor SAC for each deceased donor organ type as follows:

(*i*) By using the TH's actual organ acquisition costs for the deceased donor

organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) By dividing the costs in paragraph (b)(3)(ii)(B)(*2*)(*i*) of this section by the actual number of usable deceased donor organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the deceased donor SAC.* Costs that may be used to develop the deceased donor SAC include, but are not limited to the following:

(*1*) Costs of organs acquired from other THs or OPOs.

(*2*) Costs of transportation as specified in § 413.402(b)(8).

(*3*) Surgeons' fees for excising deceased donor organs (currently limited to $1,250 for kidneys).

* * * * *

(c) * * *

(1) * * *

(i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor non-renal organs during the IOPO's cost reporting period; and

(ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of deceased donor non-renal organs the IOPO expects to procure within its cost reporting period.

* * * * *

(2) * * *

(i) *General.* An IOPO's contractor establishes the kidney SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs the IOPO expects to incur to procure deceased donor kidneys during the IOPO's cost reporting period, divided by the, initial year projected or subsequent years' actual, number of usable deceased donor kidneys the IOPO expects to procure.

(ii) *Initial year.* The contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) *Subsequent years.* The contractor computes the kidney SAC for subsequent years using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor kidneys procured during that cost reporting period. The kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in § 413.420(d)(1).

(iv) *SAC adjustments.* The IOPO's contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

* * * * *

(3) *Billing SACs for organs generally.* When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses its SAC for each organ type and not the procuring IOPO's SAC when billing the TH receiving the organ.

■ 25. Section 413.412 is amended by revising the section heading and paragraphs (c) and (d) to read as follows:

§ 413.412 Intent to transplant, and counting en bloc, research, and unusable organs.

* * * * *

(c) *Research organs.* (1) For Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs or as total usable organs in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(2) OPOs and THs must reduce their costs to procure organs for research from total organ acquisition costs on the Medicare cost report.

(d) *Counting of unusable organs.* (1) An organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable.

(2) OPOs and THs include the cost to procure unusable organs, as described in paragraph (d)(1) of this section, in total organ acquisition costs reported on their Medicare cost report.

■ 26. Section 413.414 is amended by revising paragraphs (a), (b), (c) introductory text, (c)(1) and (2), and (c)(3)(i) and (ii) to read as follows:

§ 413.414 Medicare secondary payer and organ acquisition costs.

(a) *General principle.* If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer to the TH that performs the transplant in certain instances. To determine whether Medicare has liability to the TH that performs the transplant as a secondary payer for organ acquisition costs, it is necessary for the TH that performs the transplant to review the TH's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the TH that performs the transplant to accept the payment from the primary insurer as payment in full, and the payment the TH receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability to the TH that performs the transplant for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH that performs the transplant to submit a bill to its contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the TH must not count the organ as a Medicare usable organ.

(3) * * *

(i) The TH must pro-rate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) Only the TH that performs the transplant counts the organ as a Medicare usable organ.

* * * * *

■ 27. Section 413.416 is amended by revising paragraphs (a), (b), (c) introductory text, (c)(2) through (4), (d) introductory text, and (d)(1) to read as follows:

§ 413.416 Organ acquisition charges for kidney-paired exchanges.

(a) *Initial living donor evaluations.* When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched,

any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's Medicare cost report.

(c) *Procurement and transport of a kidney.* When a donor's TH procures and furnishes a kidney to a recipient's TH all of the following are applicable:

* * * * *

(2)(i) The donor's TH bills the recipient's TH.

(ii) The donor's TH bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's TH records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs.

(4) The recipient's TH records as part of its kidney acquisition costs—

(i) The amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's TH.

(d) *Donor's procurement occurs at recipient TH.* In a kidney-paired exchange—

(1) When a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's TH; and

* * * * *

■ 28. Section 413.418 is revised to read as follows:

§ 413.418 Amounts billed to organ procurement organizations for hospital services provided to deceased donors and included as organ acquisition costs.

(a) *General.* A donor community hospital (a Medicare-certified non-TH) and a TH incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. Organ acquisition costs include hospital services authorized by the OPO when there is consent to donate, and declaration of death has been made or death is imminent and these services must be provided prior to declaration of death. These costs must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team.

(b) *Amounts billed for organ acquisition costs.* For cost reporting periods beginning on or after February 25, 2022, when a donor community hospital or TH incurs costs for services furnished to a deceased donor, as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

■ 29. Section 413.420 is amended by revising paragraphs (a), (c)(1)(ii), (iv), and (v), (d), and (e)(2)(i) and (ii) to read as follows:

§ 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.

(a) *Principle.* (1) Covered services furnished by IOPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the TH using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by IOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

* * * * *

(c) * * *

(1) * * *

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs for services provided by the IOPO or laboratory, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or laboratory.

* * * * *

(iv) To pay to CMS amounts that have been paid by CMS to THs and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

* * * * *

(d) *Interim reimbursement.* (1) THs with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is a kidney SAC or contractor established rates, based on costs associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by THs on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all THs and contractors.

(e) * * *

(2) * * *

(i) *Retroactive adjustment.* A retroactive adjustment in the amount paid under the interim rate is made in accordance with § 413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to THs, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 30. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 31. Section 416.166 is amended by revising paragraph (d)(1) to read as follows:

§ 416.166 Covered surgical procedures.

* * * * *

(d) * * *

(1) *Pre-proposed rule CPL recommendation process.* On or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

* * * * *

■ 32. Section 416.172 is amended by adding paragraph (h) to read as follows:

§ 416.172 Adjustments to national payment rates.

* * * * *

(h) *Special payment for certain code combinations*—(1) *Eligibility.* A code combination is eligible for the payment specified in paragraph (h)(2) of this section if the code combination is—

(i) Eligible for a C–APC complexity adjustment under the OPPS; and

(ii) Comprised of a separately payable surgical procedure, that is listed on the ASC Covered Procedures list (§ 416.166), and one or more packaged add-on codes that are listed on the ASC covered procedures or ancillary services lists (§ 416.164(b)).

(2) *Calculation of payment.* (i) Except as specified in paragraph (h)(2)(ii) of this section, CMS calculates the payment for code combinations that meet the eligibility requirements in paragraph (h)(1) of this section by applying the methodology specified in § 416.171(a) to the OPPS C–APC complexity-adjusted relative weights.

(ii) For primary procedures assigned device-intensive status that are a component of a code combination that is eligible for payment under paragraph (h)(2) of this section, the primary procedure of the code combination retains its device-intensive status, and—

(A) The device portion is equivalent to the device portion of the device-intensive APC under the OPPS (§ 419.44(b)); and

(B) The non-device portion is calculated in accordance with the methodology specified in § 416.171(a).

■ 33. Section 416.174 is amended by revising paragraph (a) to read as follows:

§ 416.174 Payment for non-opioid pain management drugs and biologicals that function as supplies in surgical procedures.

(a) Eligibility for separate payment for non-opioid pain management drugs and biologicals. Beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has an FDA approved indication for pain management or analgesia.

(2) The per-day cost of the drug or biological estimated by CMS for the year exceeds the OPPS drug packaging threshold set for such year through notice and comment rulemaking.

(3) The drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in paragraph (a) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The drug or biological is not already separately payable in the OPPS or ASC payment system under a policy other than the one specified in this section.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 34. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 35. Part 419 is amended by revising the heading to read as set forth above.

■ 36. Section 419.43 is amended by adding paragraph (j) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(j) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators*—(1) *General rule.* For cost reporting periods beginning on or after January 1, 2023, CMS provides for a payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as described in paragraph (j)(2) of this section.

(2) *Amount of adjustment.* The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period as compared to other National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (j)(2) of this section in a budget neutral manner.

■ 37. Section 419.46 is amended by revising paragraph (f)(3)(iv) and adding paragraph (f)(3)(v) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(3) * * *

(iv) Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or

(v) Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters.

* * * * *

■ 38. Section 419.47 is added to read as follows:

§ 419.47 Coding and Payment for Category B Investigational Device Exemption (IDE) Studies.

(a) *Creation of a new HCPCS code for Category B IDE Studies.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under 42 CFR 405.201, when CMS determines that:

(1) The Medicare coverage IDE study criteria in 42 CFR 405.212 are met; and

(2) A new or revised code is necessary to preserve the scientific validity of such a study, such as by preventing the unblinding of study.

(b) *Payment for Category B IDE Studies.* Where CMS creates a new HCPCS code or revises an existing HCPCS code under paragraph (a) of this section, CMS will:

(1) Make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under 42 CFR 405.201; and

(2) Calculate the single packaged payment rate for the HCPCS code based on the average resources utilized for each study participant, including the frequency with which the investigational device is used in the study population.

■ 39. Section 419.83 is amended by revising paragraphs (a)(3) and (b) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) * * *

(3) The Facet Joint Interventions service category requires prior authorization beginning for service dates on or after March 1, 2023.

(b) *Adoption of the list of services and technical updates.* (1) CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or

geographic restrictions through formal notice-and-comment rulemaking.

(2) Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.

* * * * *

■ 40. Subpart K is added to read as follows:

Subpart K—Payments to Rural Emergency Hospitals (REHs)

Sec.
419.90 Basis and scope of subpart.
419.91 Definitions.
419.92 Payment to rural emergency hospitals.
419.93 Payment for an off-campus provider-based department of a rural emergency hospital.
419.94 Preclusion of administrative and judicial review.

Subpart K—Payments to Rural Emergency Hospitals (REHs)

§ 419.90 Basis and scope of subpart.

(a) *Basis.* This subpart implements sections 1861(kkk) and 1834(x) of the Act, which establish the rural emergency hospital Medicare provider type and the payment requirements applying to such entities.

(b) *Scope.* This subpart describes the methodologies used to determine payment for REH services and the monthly facility payment amount paid to REHs.

§ 419.91 Definitions.

As used in this subpart—

Rural Emergency Hospital or *REH* means an entity as defined in § 485.502 of this chapter.

Rural Emergency Hospital (REH) Services means all covered outpatient department (OPD) services, as defined in section 1833(t)(1)(B) of the Act, excluding services described in section 1833(t)(1)(B)(ii), furnished by an REH that would be paid under the OPPS when provided in a hospital paid under the OPPS for outpatient services, provided that such services are furnished consistent with the conditions of participation in §§ 485.510 through 485.544 of this chapter.

§ 419.92 Payment to rural emergency hospitals.

(a) *Payment for REH services*—(1) *Medicare payment.* A rural emergency hospital that furnishes a REH service on or after January 1, 2023, is paid an amount equal to the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service, increased by 5 percent.

(2) *Beneficiary copayment.* The beneficiary copayment for a REH service is the amount determined under section 1833(t)(8) of the Act for the equivalent covered OPD service, excluding the 5 percent payment increase described in paragraph (a)(1) of this section.

(b) *Monthly facility payment.* Effective January 1, 2023, REHs are paid a monthly facility payment equal to 1/12 of the annual additional facility payment amount described in paragraphs (b)(1) and (2) of this section.

(1) *Calculation of monthly facility payment for 2023.* For calendar year 2023, the annual additional facility payment amount is:

(i) The total amount that the Secretary determines was paid by the Medicare program and from beneficiary copayments to all critical access hospitals in calendar year 2019; minus—

(ii) The estimated total amount that the Secretary determines would have been paid by the Medicare program and from beneficiary copayments to critical access hospitals in calendar year 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during calendar year 2019; divided by—

(iii) The total number of critical access hospitals enrolled in Medicare in calendar year 2019.

(2) *Calculation of monthly facility payment for 2024 and subsequent years.* For calendar year 2024 and each subsequent calendar year, the amount of the additional annual facility payment is the amount of the preceding year's additional annual facility payment, increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

(3) *Recording and Reporting the use of the monthly facility payment.* A rural emergency hospital receiving the monthly facility payment must maintain detailed information as specified by the Secretary as to how the facility has used the monthly facility payments and must make this information available to the Secretary upon request.

(c) *Payment for services furnished by an REH that do not meet the definition of REH services.* A service furnished by an REH that does not meet the definition of an REH service under § 419.91, including a hospital service that is excluded from payment under the OPPS as described in § 419.22, is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.

(1) *Payment for ambulance services.* Ambulance services furnished by an entity owned and operated by a rural emergency hospital are paid under the ambulance fee schedule as described at section 1834(l) of the Act.

(2) *Payment for post-hospital extended care services.* Post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility are paid under the skilled nursing facility prospective payment system described at section 1888(e) of the Act.

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

(a) Items and services furnished by an off-campus provider-based department of an REH, as defined in paragraph (b) of this section, are not applicable items and services under sections 1833(t)(1)(B)(v) and (t)(21) of the Act and are paid as follows:

(1) REH services furnished by an off-campus provider-based department of an REH are paid as described in § 419.92(a)(1).

(2) Services that do not meet the definition of REH services that are furnished by an off-campus provider-based department of an REH are paid as described under § 419.92(c).

(b) For the purpose of this section, ''off-campus provider-based department of an REH'' means a ''department of a provider'' (as defined at § 413.65(a)(2) of this chapter) that is not located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a ''remote location of a hospital'' (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter.

§ 419.94 Preclusion of administrative and judicial review.

There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(a) The determination of whether a rural emergency hospital meets the requirements of this subpart.

(b) The determination of payment amounts under this subpart.

(c) The requirements established by this subpart.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 41. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 42. Amend § 424.518 by revising paragraph (a)(1)(viii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

(a) * * *

(1) * * *

(viii) Hospitals, including critical access hospitals, rural emergency hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

* * * * *

■ 43. Add § 424.575 to read as follows:

§ 424.575 Rural emergency hospitals.

(a) A rural emergency hospital (as defined in § 485.502 of this chapter) must comply with all applicable provisions in this subpart in order to enroll and maintain enrollment in Medicare.

(b) A provider that is currently enrolled in Medicare as a critical access hospital or a hospital (as defined in section 1886(d)(1)(B) of the Act) converts its existing enrollment to that of a rural emergency hospital (as defined in § 485.502 of this chapter) via a Form CMS–855A change of information application per § 424.516 rather than a Form CMS–855A initial enrollment application.

Dated: July 14, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Part III

Department of Agriculture

Forest Service

36 CFR Part 242

Department of the Interior

Fish and Wildlife Service

50 CFR Part 100

Subsistence Management Regulations for Public Lands in Alaska—2022–23 and 2023–24 Subsistence Taking of Wildlife Regulations; Final Rule

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

[Docket No. FWS–R7–SM–2020–0077; FXFR13350700640 FF07J00000 223]

RIN 1018–BF10

Subsistence Management Regulations for Public Lands in Alaska—2022–23 and 2023–24 Subsistence Taking of Wildlife Regulations

AGENCY: Forest Service, Agriculture; Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This final rule establishes regulations for seasons, harvest limits, and methods and means related to the taking of wildlife for subsistence uses in Alaska for the 2022–2023 and 2023–24 regulatory years. The Federal Subsistence Board (Board) completes the biennial process of revising subsistence hunting and trapping regulations in even-numbered years and subsistence fishing and shellfish regulations in odd-numbered years; public proposal and review processes take place during the preceding year. The Board also addresses customary and traditional use determinations during the applicable biennial cycle. This rule also revises the customary and traditional use determinations for wildlife, the general regulations, and a deferred proposal from the last fish cycle.

DATES: This rule is effective July 26, 2022.

ADDRESSES: The comments received on the proposed rule as well as the Board meeting transcripts are available at *https://www.regulations.gov* in Docket No. FWS–R7–SM–2020–0077. Board meeting transcripts are also available for review at the Office of Subsistence Management, 1011 East Tudor Road, Mail Stop 121, Anchorage, AK 99503, or on the Office of Subsistence Management website (*https://www.doi.gov/subsistence*).

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o U.S. Fish and Wildlife Service, Attention: Sue Detwiler, Assistant Regional Director, Office of Subsistence Management; (907) 786–3888 or *subsistence@fws.gov.* For questions specific to National Forest System lands, contact Gregory Risdahl, Regional Subsistence Program Leader, USDA, Forest Service, Alaska Region; (907) 302–7354 or *gregory.risdahl@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Under Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 3111–3126), the Secretary of the Interior and the Secretary of Agriculture (Secretaries) jointly implement the Federal Subsistence Management Program. This program provides a preference for take of fish and wildlife resources for subsistence uses on Federal public lands and waters in Alaska. The Secretaries published temporary regulations to carry out this program in the **Federal Register** on June 29, 1990 (55 FR 27114) and published final regulations in the **Federal Register** on May 29, 1992 (57 FR 22940). The Program has subsequently amended these regulations a number of times. Because this program is a joint effort between Interior and Agriculture, these regulations are located in two titles of the Code of Federal Regulations (CFR): title 36, ''Parks, Forests, and Public Property,'' and title 50, ''Wildlife and Fisheries,'' at 36 CFR 242.1–242.28 and 50 CFR 100.1–100.28, respectively. The regulations contain subparts as follows: Subpart A, General Provisions; Subpart B, Program Structure; Subpart C, Board Determinations; and Subpart D, Subsistence Taking of Fish and Wildlife.

Consistent with subpart B of these regulations, the Secretaries established a Federal Subsistence Board (FSB or Board) to administer the Federal Subsistence Management Program. The Board comprises:

- A Chair appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture;
- The Alaska Regional Director, U.S. Fish and Wildlife Service;
- The Alaska Regional Director, National Park Service;
- The Alaska State Director, Bureau of Land Management;
- The Alaska Regional Director, Bureau of Indian Affairs;
- The Alaska Regional Forester, USDA Forest Service (USFS); and
- Two public members appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture.

Through the Board, these agencies participate in the development of regulations for subparts C and D, which, among other things, set forth program eligibility and specific harvest seasons and limits.

In administering the program, the Secretaries divided Alaska into 10 subsistence resource regions, each of which is represented by a Regional Advisory Council (Council or RAC). The RACs provide a forum for rural residents with personal knowledge of local conditions and resource requirements to have a meaningful role in the subsistence management of fish and wildlife on Federal public lands in Alaska. The Council members represent varied geographical, cultural, and user interests within each region.

The Board addresses customary and traditional (C&T) use determinations during the applicable biennial cycle. Section __.24 (customary and traditional use determinations) was originally published in the **Federal Register** on May 29, 1992 (57 FR 22940). The regulations at 36 CFR 242.4 and 50 CFR 100.4 define ''customary and traditional use'' as ''a long-established, consistent pattern of use, incorporating beliefs and customs which have been transmitted from generation to generation . . . .'' Since 1992, the Board has made a number of customary and traditional use determinations at the request of affected subsistence users. Those modifications, along with some administrative corrections, were published in the **Federal Register** as follows:

MODIFICATIONS TO §__.24

Federal Register citation	Date of publication	Rule made changes to the following provisions of __.24
59 FR 27462	May 27, 1994	Wildlife and Fish/Shellfish.
59 FR 51855	October 13, 1994	Wildlife and Fish/Shellfish.
60 FR 10317	February 24, 1995	Wildlife and Fish/Shellfish.
61 FR 39698	July 30, 1996	Wildlife and Fish/Shellfish.
62 FR 29016	May 29, 1997	Wildlife and Fish/Shellfish.

MODIFICATIONS TO §__.24—Continued

Federal Register citation	Date of publication	Rule made changes to the following provisions of __.24
63 FR 35332	June 29, 1998	Wildlife and Fish/Shellfish.
63 FR 46148	August 28, 1998	Wildlife and Fish/Shellfish.
64 FR 1276	January 8, 1999	Fish/Shellfish.
64 FR 35776	July 1, 1999	Wildlife.
65 FR 40730	June 30, 2000	Wildlife.
66 FR 10142	February 13, 2001	Fish/Shellfish.
66 FR 33744	June 25, 2001	Wildlife.
67 FR 5890	February 7, 2002	Fish/Shellfish.
67 FR 43710	June 28, 2002	Wildlife.
68 FR 7276	February 12, 2003	Fish/Shellfish.
69 FR 5018	February 3, 2004	Fish/Shellfish.
69 FR 40174	July 1, 2004	Wildlife.
70 FR 13377	March 21, 2005	Fish/Shellfish.
70 FR 36268	June 22, 2005	Wildlife.
71 FR 15569	March 29, 2006	Fish/Shellfish.
71 FR 37642	June 30, 2006	Wildlife.
72 FR 12676	March 16, 2007	Fish/Shellfish.
72 FR 73426	December 27, 2007	Wildlife/Fish.
73 FR 35726	June 26, 2008	Wildlife.
74 FR 14049	March 30, 2009	Fish/Shellfish.
75 FR 37918	June 30, 2010	Wildlife.
76 FR 12564	March 8, 2011	Fish/Shellfish.
77 FR 35482	June 13, 2012	Wildlife.
79 FR 35232	June 19, 2014	Wildlife.
81 FR 52528	August 8, 2016	Wildlife.
83 FR 3079	January 23, 2018	Fish.
83 FR 50758	October 9, 2018	Wildlife.
84 FR 39744	August 12, 2019	Fish.
85 FR 74796	November 23, 2020	Wildlife.

Current Rule

The Departments published a proposed rule on February 23, 2021 (86 FR 10899), to amend the wildlife sections of subparts C and D of 36 CFR part 242 and 50 CFR part 100. The proposed rule opened a comment period, which closed on May 24, 2021. The Departments advertised the proposed rule by mail, email, web page, social media, radio, and newspaper. During that period, the RACs met and, in addition to other Council business, generated proposals and received suggestions for proposals from the public. The Board received 58 proposals for changes to subparts C and D and reviewed 15 wildlife closure reviews. In addition to the proposals listed below, 4 comments on the proposed rule were received from the public. Three were in support of the proposed rule based on conservation concerns and providing a subsistence lifestyle for rural Alaskans. The one comment in opposition, stated that wildlife should be ''left alone and not disturbed''. Title VIII of ANILCA reguires the Secretaries to promulgate regulations and provide for a preference on the take of fish and wildlife resources for nonwasteful subsistence uses.

After the comment period closed, the Board prepared a booklet describing the proposals and distributed it to the public. The proposals were also available online. The public then had an additional 45 days in which to comment on the proposals for changes to the regulations.

The 10 RACs met again, received public comments, and formulated their recommendations to the Board on proposals for their respective regions. The Councils had a substantial role in reviewing the proposed rule and making recommendations for the final rule. Moreover, a Council Chair, or a designated representative, presented each Council's recommendations at the Board meeting that was held April 12–15, 2022. These final regulations reflect Board review and consideration of RAC recommendations, Tribal and Alaska Native corporation consultations, public comments, and the Alaska Department of Fish and Game (ADF&G) recommendations. The public received extensive opportunity to review and comment on all changes.

Of the 58 proposals, one was withdrawn by the proponent, one was a deferred proposal from the previous rulemaking cycle pertaining to fish regulations, 25 were on the Board's non-consensus agenda, and 31 were on the consensus agenda. The consensus agenda is made up of proposals for which there is agreement among the affected Councils, a majority of the Interagency Staff Committee, and the ADF&G concerning a proposed regulatory action. Anyone may request that the Board remove a proposal from the consensus agenda and place it on the non-consensus agenda. The Board votes en masse on the consensus agenda after deliberation and action on the non-consensus agenda.

Board actions on each proposal and closure review are listed below. When making decisions, the Board may use, but is not limited to, the following guidelines for consideration of whether a proposal: provides a subsistence priority on public lands, is supported by substantial scientific and traditional ecological knowledge (TEK) evidence, recognizes principles of fish and wildlife conservation, provides opportunity, and would not be detrimental or place undue burden on rural Alaskan subsistence users.

Analysis and justification for the action taken on each proposal are available for review at the Office of Subsistence Management, 1011 East Tudor Road, Mail Stop 121, Anchorage, Alaska 99503, or on the Federal Subsistence Management Programs website (*http://www.doi.gov/subsistence/index.cfm*) or at *https://www.regulations.gov* in Docket No. FWS–R7–SM–2020–0077.

Proposal No.	Species or issue	Unit(s)	General description	Federal Subsistence Board action
WP22–01	General regulations	Statewide	Define who is/is not a participant in a community harvest program.	Adopt.
WP22–02	Various	6, 9, 10, 22, 23, 26	Rescind restrictions for designated hunters in areas with community harvest systems in place.	Adopt.
WP22–xx	Moose	3	Require the use of locking tags	Withdrawn.
WP22–03	Wolves	2	Establish precise requirements for information taking for the harvest of wolves.	Adopt with Office of Subsistence Management (OSM) and Southcentral RAC (SCRAC) modification to remove the 7-day reporting requirement.
WP22–04	Elk	1–4	Establish a hunt with a year-round season.	Adopt.
WP22–05	Elk	3	Establish a hunt under a draw permit system.	Reject.
WP22–06	Moose	3	Establish a quota and place restrictions on harvest limit.	Reject.
WP22–07	Deer	4	Closure to non-federally qualified users, Admiralty Island.	Defer until 2023 FSB winter meeting to gather more data and address options to prevent user conflict.
WP22–08	Deer	4	Place a harvest restriction on non-federally qualified users.	Defer until 2023 FSB winter meeting to gather more data and address options to prevent user conflict.
WP22–09	Deer	4	Closure to non-federally qualified users, Lisianki Strait.	Reject.
WP22–10	Deer	4	Reduce bag limit to non-federally qualified subsistence hunters.	Defer until 2023 FSB winter meeting to gather more data and address options to prevent user conflict.
WP22–11	Goat	5A	Rescind the harvest quota	Adopt with OSM modification to remove the language describing an announcement of the quota from unit-specific regulations and maintain in the delegation of authority letter only.
WCR22–01	Deer	2	Prince of Wales Island closed Aug. 1–15, except for use by federally qualified subsistence users; non-federally qualified users may harvest only two bucks.	Maintain status quo.
WCR22–02	Moose	5	Unit 5A, except Nunatak Bench—seasonal closures to non-federally qualified users.	Maintain status quo.
WP22–12	Deer	6D	Revise hunt areas and season dates.	Adopt with SCRAC modification to restrict the January season harvest limit to one deer in all of Unit 6.
WP22–13	Deer	6	Add deer to designated hunter list	Reject.
WP22–14	Black bear	6	Increase harvest limit	Reject.
WP22–15	General trapping	7	Adjust language to restrict trapping in a portion of USFS lands in Unit 7.	Reject.
WP22–16	Moose	15A, 15B	C&T use determination (Moose Pass).	Adopt.
WP22–17	Moose	7	C&T use determination (Moose Pass).	Adopt.
WP22–18	Moose	15A, 15B	C&T use determination (Moose Pass).	Adopt.
WP22–19	Moose	15C	C&T use determination (Moose Pass).	Reject.
WP22–20	Moose	15C	C&T use determination (Cooper Landing).	Reject.
WP22–21	Caribou	7	C&T use determination (Moose Pass).	Adopt.
WP22–22	Caribou	15B, 15C	C&T use determination (Moose Pass).	Adopt as modified by SCRAC to remove Unit 15C.
WP22–23	Goat	7	C&T use determination (Moose Pass).	Adopt.
WP22–24	Goat	15	C&T use determination (Moose Pass).	Adopt as modified by SCRAC to remove Unit 15C.
WP22–25a	Sheep	7	C&T use determination (Cooper Landing).	Adopt.
WP22–25b	Sheep	7	Establish hunt	Adopt with OSM modification to establish a Federal drawing permit hunt for sheep in Unit 7 with a harvest limit of one ram with full curl horn or larger, and delegate authority to the Seward District Ranger of the Chugach National Forest to close the season and set the harvest quota, the number of permits to be issued, and any needed permit conditions via delegation of authority letter only.
WP22–26a	Sheep	7	C&T use determination (Moose Pass).	Adopt.
WP22–26b	Sheep	7	Establish hunt	Take no action.
WP22–27	Sheep	15	C&T use determination (Cooper Landing and Ninilchik).	Adopt with SCRAC modification to recognize C&T determination of sheep for Cooper Landing only in Units 15A and 15B (remove 15C).
WP22–28	Moose	7	Extend hunting season by 5 days from Sep. 25.	Adopt with SCRAC modification to shift the season to Aug. 20–Sep. 25.
WP22–29	Moose	7	Extend hunting season	Take no action.
WP22–30	Moose	15	Extend hunting season	Adopt with SCRAC modification to shift the season to Aug. 20–Sep. 25.
WP22–31	Moose	15	Extend hunting season	Take no action.

Proposal No.	Species or issue	Unit(s)	General description	Federal Subsistence Board action
WP22–32	Bear, Caribou, Sheep, Moose.	15	C&T use determination (North Fork Rural Community).	Reject.
WP22–33	Black bear	11, 12	Rescind sealing requirement	Adopt.
WP22–34	Sheep	11, 12	Change salvage requirements for sheep; meat-on-bone salvage requirement.	Reject.
WP22–35	Caribou	11	Establish a may-be-announced season.	Adopt with OSM modification to delegate authority to the WRST superintendent to announce season dates, harvest quotas, and the number of permits to be issued; to define harvest areas; and to open and close the season via a delegation of authority letter only.
WP22–36	Moose, Caribou	11, 12, 13	Incorporate WSA 20–02 temporary regulations into permanent regulations.	Adopt with the OSM modification and a Board amendment to define the hunt area for the Ahtna Intertribal Resource Commission community harvest system in Unit 12.
WP22–37	Ptarmigan	9D	C&T use determination (Cold Bay, King Cove, Sand Point, Belkofski, Sanak, Pauloff Harbor, Unga, Nelson Lagoon).	Adopt with OSM modification; all residents of Unit 9D.
WP22–38a	Caribou	10	Add Cold Bay and Nelson Lagoon to existing C&T determination.	Adopt.
WP22–38b	Caribou	10	Allow federally qualified subsistence users access to Federal public lands for the taking of caribou.	Adopt with OSM and Kodiak/Aleutians RAC modification; to remove the closure from the unit-specific regulations and delegate authority to the Izembek National Wildlife Refuge (NWR) Refuge Manager to open and close Federal public lands to non-federally qualified users annually based on the current population status of the Unimak caribou herd in consultation with ADF&G staff via delegation of authority letter.
WP22–39	Hare	9, 17	Establish specific harvest regulations for Alaska hare.	Adopt with OSM modification revising the definition of hare and with Bristol Bay RAC to change the season closing date to March 31.
WP22–40	Wolves, Wolverine	9B, 9C 17B, 17C	Allow the use of snowmachines to position wolves and wolverines.	Defer to Jan 2023 FSB meeting to allow additional time to revise text.
WP22–41	Caribou	9A, 9C	Delegate authority to the Togiak NWR manager to open/close seasons, announce harvest limits, and set sex restrictions via delegation of authority letter.	Adopt.
WCR22–05	Moose	9	9C, Naknek River—Dec. closure to non-federally qualified users.	Maintain status quo.
WCR22–07	Caribou	17	Nushagak Peninsula—closed to non-federally qualified users unless pop. >900 caribou.	Maintain status quo.
WP22–42	Moose	18 Remainder	Increase the harvest limit	Adopt.
WP22–43	Moose	18	Revise the delegation of authority for the Refuge Manager to adjust harvest limits based on water levels.	Reject.
WP22–44	Moose	18	Change season dates and establish a may-be-announced season.	Adopt with OSM modification to revise the regulatory language and to delegate authority to the Yukon Delta NWR manager to announce the winter season and set harvest quotas via delegation of authority letter only.
WP22–45	Hare	18, 22, 23	Establish specific harvest regulations for Alaska hare.	Adopt with OSM modification to shorten the season to Aug. 1–May 31 and to modify the definition of hare.
WP22–46	Brown bear	24B	Increase harvest limit	Adopt.
WP22–47	Caribou	22	Allow the harvest of calves	Reject.
WP22–48	Moose	22A	Revise hunt area boundaries	Adopt.
WP22–49	Moose	22A	Remove federally qualified restriction; change to match hunting season established for residents and nonresidents by Alaska Board of Game.	Adopt.
WCR22–09b	Moose	22	Unit 22A Unalakleet drainage—closed except to Unalakleet residents.	Modify the closure; only open to federally qualified subsistence users.
WCR22–09c	Moose	22	Unit 22A remainder—seasonal closure to non-federally qualified users.	Maintain status quo.
WCR22–11/12	Moose	22	WCR22–11: Unit 22B, W. Darby Mtns–Fall—closed to non-federally qualified users. WCR22–12: Unit 22B, W Darby Mtns–Winter—closed except by White Mtn. and Golovin.	Maintain status quo.
WCR22–13	Moose	22	Unit 22D, Kougarok, Kuzitrin, Pilgrim drainages—closed except by Unit 22C and 22D residents.	Maintain status quo.

Proposal No.	Species or issue	Unit(s)	General description	Federal Subsistence Board action
WCR22–14	Moose	22	Unit 22D, W Tisuk and Canyon drainage—closed except by Unit 22C and 22D residents.	Maintain status quo.
WCR22–16	Moose	22	Unit 22E—closed to non-federally qualified users.	Maintain status quo.
WP22–50	Beaver	23	Trapping: Increase harvest limit to ''no limit''.	Adopt with OSM modification to combine Unit 23 trapping areas.
WCR22–18	Sheep	23	Unit 23–Baird Mtns—closed to non-federally qualified users.	Maintain status quo.
WCR22–27	Musk ox	23	Unit 23, Cape Krusenstern National Monument—closed to residents of Point Hope.	Eliminate closure as recommended by OSM.
WCR22–45	Caribou	23	Unit 23–Noatak—closed to non-federally qualified users.	Maintain status quo.
WP22–51	Moose	20B	Remove Minto Flats registration hunt.	Adopt.
WP22–52	Moose	25A	Lengthen season	Adopt with Eastern Interior RAC and ADF&G modification to extend the season in the Coleen, Firth, and Old Crow River drainages only.
WP22–53	Arctic fox	25	Establish season/harvest limits	Adopt.
WCR22–22	Moose	25	Unit 25D west—closed except by 25D west residents.	Maintain status quo.
WP22–54	Moose	26A	Revise the hunt area	Adopt with OSM modification to revise the hunt area descriptor.
WP22–55	Musk ox	26A	Establish a hunt	Adopt with OSM modification to revise the hunt area descriptor, require drawing permits, and delegate authority to manage the hunt to the BLM Arctic District Office Manager.
WP22–56	Brown bear	26A	Harvest limit	Adopt.
WCR22–25	Musk ox	26	Unit 26C—closed except by Kaktovik residents.	Maintain status quo.
FP21–10	Salmon	Lower Copper River Harvest Area.	Implement salmon subsistence fishery; harvest limit.	Adopt with OSM modification and Board amendment to allow fishing by dip net and rod and reel only, delay the start of the fishery to June 1, and prohibit dip-netting by boats.

These final regulations reflect Board review and consideration of Regional Advisory Council recommendations, Tribal and Alaska Native corporation consultations, public and ADF&G comments. The proposals indicated above as ''adopted'' are reflected in the rule portion of this document as revisions to the subsistence management regulations. Because this rule concerns public lands managed by an agency or agencies in both the Departments of Agriculture and the Interior, identical text will be incorporated into 36 CFR part 242 and 50 CFR part 100.

Conformance With Statutory and Regulatory Authorities

Administrative Procedure Act Compliance

The Board has provided extensive opportunity for public input and involvement in compliance with Administrative Procedure Act requirements, including publishing a proposed rule in the **Federal Register**, participation in multiple Regional Council meetings, additional public review and comment on all proposals for regulatory change, and opportunity for additional public comment during the Board meeting prior to deliberation. Additionally, an administrative mechanism exists (and has been used by the public) to request reconsideration of the Board's decision on any particular proposal for regulatory change (36 CFR 242.20 and 50 CFR 100.20). Therefore, the Board believes that sufficient public notice and opportunity for involvement have been given to affected persons regarding Board decisions.

In the more than 30 years that the Program has been operating, no benefit to the public has been demonstrated by delaying the effective date of the subsistence regulations. A lapse in regulatory control could affect the continued viability of fish or wildlife populations and future subsistence opportunities for rural Alaskans, and would generally fail to serve the overall public interest. Therefore, the Board finds good cause pursuant to 5 U.S.C. 553(d)(3) to make this rule effective upon the date set forth in **DATES** to ensure continued operation of the subsistence program.

National Environmental Policy Act Compliance

A Draft Environmental Impact Statement that described four alternatives for developing a Federal Subsistence Management Program was distributed for public comment on October 7, 1991. The Final Environmental Impact Statement (FEIS) was published on February 28, 1992. The Record of Decision (ROD) on Subsistence Management for Federal Public Lands in Alaska was signed April 6, 1992. The selected alternative in the FEIS (Alternative IV) defined the administrative framework of an annual regulatory cycle for subsistence regulations.

A 1997 environmental assessment dealt with the expansion of Federal jurisdiction over fisheries and is available at the office listed under **FOR FURTHER INFORMATION CONTACT**. The Secretary of the Interior, with concurrence of the Secretary of Agriculture, determined that expansion of Federal jurisdiction does not constitute a major Federal action significantly affecting the human environment and, therefore, signed a Finding of No Significant Impact.

Section 810 of ANILCA

An ANILCA section 810 analysis was completed as part of the FEIS process on the Federal Subsistence Management Program. The intent of all Federal subsistence regulations is to accord subsistence uses of fish and wildlife on public lands a priority over the taking of fish and wildlife on such lands for other purposes, unless restriction is necessary to conserve healthy fish and wildlife populations. The final section 810 analysis determination appeared in the April 6, 1992, ROD and concluded that the Program, under Alternative IV with an annual process for setting

subsistence regulations, may have some local impacts on subsistence uses, but will not likely restrict subsistence uses significantly.

During the subsequent environmental assessment process for extending fisheries jurisdiction, an evaluation of the effects of this rule was conducted in accordance with section 810. That evaluation also supported the Secretaries' determination that the rule will not reach the ''may significantly restrict'' threshold that would require notice and hearings under ANILCA section 810(a).

Paperwork Reduction Act of 1995 (PRA)

This final rule does not contain any new collections of information that require Office of Management and Budget (OMB) approval under the PRA (44 U.S.C. 3501 *et seq.*). OMB has reviewed and approved the collections of information associated with the subsistence regulations at 36 CFR part 242 and 50 CFR part 100, and assigned OMB Control Number 1018–0075, with an expiration date of January 31, 2024. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations, or governmental jurisdictions. In general, the resources to be harvested under this rule are already being harvested and consumed by the local harvester and do not result in an additional dollar benefit to the economy. However, we estimate that two million pounds of meat are harvested by subsistence users annually and, if given an estimated dollar value of $3.00 per pound, this amount would equate to about $6 million in food value Statewide. Based upon the amounts and values cited above, the Departments certify that this rulemaking will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

Under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*), this rule is not a major rule. It does not have an effect on the economy of $100 million or more, will not cause a major increase in costs or prices for consumers, and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Executive Order 12630

Title VIII of ANILCA requires the Secretaries to administer a subsistence priority on public lands. The scope of this Program is limited by definition to certain public lands. Likewise, these regulations have no potential takings of private property implications as defined by Executive Order 12630.

Unfunded Mandates Reform Act

The Secretaries have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.,* that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. The implementation of this rule is by Federal agencies, and there is no cost imposed on any State or local entities or tribal governments.

Executive Order 12988

The Secretaries have determined that these regulations meet the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988, regarding civil justice reform.

Executive Order 13132

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. Title VIII of ANILCA precludes the State from exercising subsistence management authority over fish and wildlife resources on Federal lands unless it meets certain requirements.

Executive Order 13175

The Alaska National Interest Lands Conservation Act, Title VIII, does not provide specific rights to tribes for the subsistence taking of wildlife, fish, and shellfish. However, the Board provided federally recognized Tribes and Alaska Native corporations opportunities to consult on this rule. Consultation with Alaska Native corporations are based on Public Law 108–199, div. H, Sec. 161, Jan. 23, 2004, 118 Stat. 452, as amended by Public Law 108–447, div. H, title V, Sec. 518, Dec. 8, 2004, 118 Stat. 3267, which provides that: ''The Director of the Office of Management and Budget and all Federal agencies shall hereafter consult with Alaska Native corporations on the same basis as Indian tribes under Executive Order No. 13175.''

The Secretaries, through the Board, provided a variety of opportunities for consultation: commenting on proposed changes to the existing rule; engaging in dialogue at the Regional Council meetings; engaging in dialogue at the Board's meetings; and providing input in person, by mail, email, or phone at any time during the rulemaking process.

On April 12, 2022, the Board provided federally recognized Tribes and Alaska Native Corporations a specific opportunity to consult on this rule prior to the start of its public regulatory meeting. Federally recognized Tribes and Alaska Native Corporations were notified by mail and telephone and were given the opportunity to attend via teleconference.

Executive Order 13211

This Executive Order requires agencies to prepare statements of energy effects when undertaking certain actions. However, this rule is not a significant regulatory action under E.O. 13211, affecting energy supply, distribution, or use, and no statement of energy effects is required.

Drafting Information

Theo Matuskowitz drafted these regulations under the guidance of Sue Detwiler of the Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service,

Anchorage, Alaska. Additional assistance was provided by

- Chris McKee, Alaska State Office, Bureau of Land Management;
- Kim Jochum, Alaska Regional Office, National Park Service;
- Dr. Glenn Chen, Alaska Regional Office, Bureau of Indian Affairs;
- Jill Klein, Alaska Regional Office, U.S. Fish and Wildlife Service; and
- Gregory Risdahl, Alaska Regional Office, USDA Forest Service.

List of Subjects

36 CFR Part 242

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

Regulation Promulgation

For the reasons set out in the preamble, the Federal Subsistence Board amends title 36, part 242, and title 50, part 100, of the Code of Federal Regulations, as set forth below.

PART __—SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA

■ 1. The authority citation for 36 CFR part 242 and 50 CFR part 100 continues to read as follows:

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3586; 43 U.S.C. 1733.

Subpart C—Board Determinations

■ 2. Amend § __.24 by revising table 1 to paragraph (a)(1) to read as follows:

§ __.24 Customary and traditional use determinations.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Area	Species	Determination
Unit 1	Black Bear	Residents of Units 1–5.
Unit 1	Brown Bear	Residents of Units 1–5.
Unit 1	Deer	Residents of Units 1–5.
Unit 1	Goat	Residents of Units 1–5.
Unit 1	Moose	Residents of Units 1–5.
Unit 2	Black Bear	Residents of Units 1–5.
Unit 2	Deer	Residents of Units 1–5.
Unit 3	Black Bear	Residents of Units 1–5.
Unit 3	Brown Bear	Residents of Units 1–5.
Unit 3	Deer	Residents of Units 1–5.
Unit 3	Elk	Residents of Units 1–5.
Unit 3	Moose	Residents of Units 1–5.
Unit 4	Brown Bear	Residents of Units 1–5.
Unit 4	Deer	Residents of Units 1–5.
Unit 4	Goat	Residents of Units 1–5.
Unit 5	Black Bear	Residents of Units 1–5.
Unit 5	Brown Bear	Residents of Units 1–5.
Unit 5	Deer	Residents of Units 1–5.
Unit 5	Goat	Residents of Units 1–5.
Unit 5	Moose	Residents of Unit 5A.
Unit 5	Wolf	Residents of Unit 5A.
Unit 6A	Black Bear	Residents of Yakutat and Units 6C and 6D, excluding residents of Whittier.
Unit 6, remainder	Black Bear	Residents of Units 6C and 6D, excluding residents of Whittier.
Unit 6	Brown Bear	No Federal subsistence priority.
Unit 6A	Goat	Residents of Units 5A, 6C, Chenega Bay, and Tatitlek.
Unit 6C and Unit 6D	Goat	Residents of Units 6C and 6D.
Unit 6A	Moose	Residents of Units 5A, 6A, 6B, and 6C.
Unit 6B and Unit 6C	Moose	Residents of Units 6A, 6B, and 6C.
Unit 6D	Moose	Residents of Unit 6D.
Unit 6A	Wolf	Residents of Units 5A, 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 6, remainder	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 7	Brown Bear	No Federal subsistence priority.
Unit 7	Caribou	Residents of Cooper Landing, Hope, and Moose Pass.
Unit 7, Brown Mountain hunt area	Goat	Residents of Port Graham and Nanwalek.
Unit 7, remainder	Goat	Residents of Chenega Bay, Cooper Landing, Hope, Moose Pass, Nanwalek, Ninilchik, Port Graham, Seldovia, and Tatilek.
Unit 7	Moose	Residents of Chenega Bay, Cooper Landing, Hope, Moose Pass, and Tatitlek.
Unit 7	Sheep	Residents of Cooper Landing and Moose Pass.
Unit 7	Ruffed Grouse	No Federal subsistence priority.
Unit 8	Brown Bear	Residents of Old Harbor, Akhiok, Larsen Bay, Karluk, Ouzinkie, and Port Lions.
Unit 8	Deer	Residents of Unit 8.
Unit 8	Elk	Residents of Unit 8.
Unit 8	Goat	No Federal subsistence priority.
Unit 9D	Bison	No Federal subsistence priority.
Unit 9A and Unit 9B	Black Bear	Residents of Units 9A, 9B, 17A, 17B, and 17C.
Unit 9A	Brown Bear	Residents of Pedro Bay.
Unit 9B	Brown Bear	Residents of Unit 9B.
Unit 9C	Brown Bear	Residents of Unit 9C, Igiugig, Kakhonak, and Levelock.
Unit 9D	Brown Bear	Residents of Units 9D and 10 (Unimak Island).

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Area	Species	Determination
Unit 9E	Brown Bear	Residents of Chignik, Chignik Lagoon, Chignik Lake, Egegik, Ivanof Bay, Perryville, Pilot Point, Ugashik, and Port Heiden/Meshik.
Unit 9A and Unit 9B	Caribou	Residents of Units 9B, 9C, and 17.
Unit 9C	Caribou	Residents of Units 9B, 9C, 17, and Egegik.
Unit 9D	Caribou	Residents of Unit 9D, Akutan, and False Pass.
Unit 9E	Caribou	Residents of Units 9B, 9C, 9E, 17, Nelson Lagoon, and Sand Point.
Unit 9A, Unit 9B, Unit 9C, and Unit 9E	Moose	Residents of Units 9A, 9B, 9C, and 9E.
Unit 9D	Moose	Residents of Cold Bay, False Pass, King Cove, Nelson Lagoon, and Sand Point.
Unit 9D	Ptarmigan	Residents of Unit 9D.
Unit 9B	Sheep	Residents of Iliamna, Newhalen, Nondalton, Pedro Bay, Port Alsworth, and Lake Clark National Park and Preserve within Unit 9B.
Unit 9	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 9A, Unit 9B, Unit 9C, and Unit 9E	Beaver	Residents of Units 9A, 9B, 9C, 9E, and 17.
Unit 10 Unimak Island	Brown Bear	Residents of Units 9D and 10 (Unimak Island).
Unit 10 Unimak Island	Caribou	Residents of Akutan, Cold Bay, False Pass, King Cove, Nelson Lagoon, and Sand Point.
Unit 10, remainder	Caribou	No Federal subsistence priority.
Unit 10	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 11	Bison	No Federal subsistence priority.
Unit 11, north of the Sanford River	Black Bear	Residents of Chistochina, Chitina, Copper Center, Gakona, Glennallen, Gulkana, Kenny Lake, Mentasta Lake, Slana, Tazlina, Tonsina, and Units 11 and 12.
Unit 11, remainder	Black Bear	Residents of Chistochina, Chitina, Copper Center, Gakona, Glennallen, Gulkana, Kenny Lake, Mentasta Lake, Nabesna Road (mileposts 25–46), Slana, Tazlina, Tok Cutoff Road (mileposts 79–110), Tonsina, and Unit 11.
Unit 11, north of the Sanford River	Brown Bear	Residents of Chistochina, Chitina, Copper Center, Gakona, Glennallen, Gulkana, Kenny Lake, Mentasta Lake, Slana, Tazlina, Tonsina, and Units 11 and 12.
Unit 11, remainder	Brown Bear	Residents of Chistochina, Chitina, Copper Center, Gakona, Glennallen, Gulkana, Kenny Lake, Mentasta Lake, Nabesna Road (mileposts 25–46), Slana, Tazlina, Tok Cutoff Road (mileposts 79–110), Tonsina, and Unit 11.
Unit 11, north of the Sanford River	Caribou	Residents of Units 11, 12, 13A–D, Chickaloon, Healy Lake, and Dot Lake.
Unit 11, remainder	Caribou	Residents of Units 11, 13A–D, and Chickaloon.
Unit 11	Goat	Residents of Unit 11, Chitina, Chistochina, Copper Center, Gakona, Glennallen, Gulkana, Kenny Lake, Mentasta Lake, Slana, Tazlina, Tonsina, and Dot Lake, Tok Cutoff Road (mileposts 79–110 Mentasta Pass), and Nabesna Road (mileposts 25–46).
Unit 11, north of the Sanford River	Moose	Residents of Units 11, 12, 13A–D, Chickaloon, Healy Lake, and Dot Lake.
Unit 11, remainder	Moose	Residents of Units 11, 13A–D, and Chickaloon.
Unit 11, north of the Sanford River	Sheep	Residents of Unit 12, Chistochina, Chitina, Copper Center, Dot Lake, Gakona, Glennallen, Gulkana, Healy Lake, Kenny Lake, Mentasta Lake, Slana, McCarthy/South Wrangell/South Park, Tazlina, Tonsina, residents along the Nabesna Road—Mileposts 0–46 (Nabesna Road), and residents along the McCarthy Road—Mileposts 0–62 (McCarthy Road).
Unit 11, remainder	Sheep	Residents of Chisana, Chistochina, Chitina, Copper Center, Gakona, Glennallen, Gulkana, Kenny Lake, Mentasta Lake, Slana, McCarthy/South Wrangell/South Park, Tazlina, Tonsina, residents along the Tok Cutoff—Milepost 79–110 (Mentasta Pass), residents along the Nabesna Road—Mileposts 0–46 (Nabesna Road), and residents along the McCarthy Road—Mileposts 0–62 (McCarthy Road).
Unit 11	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 11	Grouse (Spruce, Blue, Ruffed and Sharp-tailed).	Residents of Units 11, 12, 13, and Chickaloon, 15, 16, 20D, 22, and 23.
Unit 11	Ptarmigan (Rock, Willow and White-tailed).	Residents of Units 11, 12, 13, Chickaloon, 15, 16, 20D, 22, and 23.
Unit 12	Brown Bear	Residents of Unit 12, Dot Lake, Chistochina, Gakona, Mentasta Lake, and Slana.
Unit 12	Caribou	Residents of Unit 12, Chistochina, Dot Lake, Healy Lake, and Mentasta Lake.
Unit 12, that portion within the Tetlin National Wildlife Refuge and those lands within the Wrangell-St. Elias National Preserve north and east of a line formed by the Pickerel Lake Winter Trail from the Canadian border to Pickerel Lake.	Moose	Residents of Units 12 and 13C, Dot Lake, and Healy Lake.
Unit 12, that portion east of the Nabesna River and Nabesna Glacier, and south of the Winter Trail running southeast from Pickerel Lake to the Canadian border.	Moose	Residents of Units 12 and 13C and Healy Lake.

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Area	Species	Determination
Unit 12, remainder	Moose	Residents of Unit 11 north of 62nd parallel, Units 12 and 13A–D, Chickaloon, Dot Lake, and Healy Lake.
Unit 12	Sheep	Residents of Unit 12, Chistochina, Dot Lake, Healy Lake, Mentasta Lake, and Slana.
Unit 12	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 13	Brown Bear	Residents of Unit 13 and Slana.
Unit 13B	Caribou	Residents of Units 11, 12 (along the Nabesna Road and Tok Cutoff Road, mileposts 79–110), 13, 20D (excluding residents of Fort Greely), and Chickaloon.
Unit 13C	Caribou	Residents of Units 11, 12 (along the Nabesna Road and Tok Cutoff Road, mileposts 79–110), 13, Chickaloon, Dot Lake, and Healy Lake.
Unit 13A and Unit 13D	Caribou	Residents of Units 11, 12 (along the Nabesna Road), 13, and Chickaloon.
Unit 13E	Caribou	Residents of Units 11, 12 (along the Nabesna Road), 13, Chickaloon, McKinley Village, and the area along the Parks Highway between mileposts 216 and 239 (excluding residents of Denali National Park headquarters).
Unit 13D	Goat	No Federal subsistence priority.
Unit 13A and Unit 13D	Moose	Residents of Unit 13, Chickaloon, and Slana.
Unit 13B	Moose	Residents of Units 13 and 20D (excluding residents of Fort Greely) and Chickaloon and Slana.
Unit 13C	Moose	Residents of Units 12 and 13, Chickaloon, Healy Lake, Dot Lake, and Slana.
Unit 13E	Moose	Residents of Unit 13, Chickaloon, McKinley Village, Slana, and the area along the Parks Highway between mileposts 216 and 239 (excluding residents of Denali National Park headquarters).
Unit 13D	Sheep	No Federal subsistence priority.
Unit 13	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 13	Grouse (Spruce, Blue, Ruffed Sharp-tailed).	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22 and 23.
Unit 13	Ptarmigan (Rock, Willow and White-tailed).	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22 and 23.
Unit 14C	Brown Bear	No Federal subsistence priority.
Unit 14	Goat	No Federal subsistence priority.
Unit 14	Moose	No Federal subsistence priority.
Unit 14A and Unit 14C	Sheep	No Federal subsistence priority.
Unit 15A and Unit 15B	Black Bear	Residents of Ninilchik.
Unit 15C	Black Bear	Residents of Ninilchik, Port Graham, and Nanwalek.
Unit 15	Brown Bear	Residents of Ninilchik.
Unit 15B	Caribou	Residents of Cooper Landing, Hope, Nanwalek, Ninilchik, Moose Pass, Port Graham, and Seldovia.
Unit 15C	Caribou	Residents of Cooper Landing, Hope, Nanwalek, Ninilchik, Port Graham, and Seldovia.
Unit 15A and Unit 15B	Goat	Residents of Cooper Landing, Hope, Moose Pass, Nanwalek, Ninilchik, Port Graham, and Seldovia.
Unit 15C	Goat	Residents of Cooper Landing, Hope, Nanwalek, Ninilchik, Port Graham, and Seldovia.
Unit 15A and Unit 15B	Moose	Residents of Cooper Landing, Ninilchik, Moose Pass, Nanwalek, Port Graham, and Seldovia.
Unit 15C	Moose	Residents of Ninilchik, Nanwalek, Port Graham, and Seldovia.
Unit 15A and Unit 15B	Sheep	Residents of Cooper Landing and Ninilchik.
Unit 15C	Sheep	Residents of Ninilchik.
Unit 15	Ptarmigan (Rock, Willow, and White-tailed).	Residents of Unit 15.
Unit 15	Grouse (Spruce)	Residents of Unit 15.
Unit 15	Grouse (Ruffed)	No Federal subsistence priority.
Unit 16B	Black Bear	Residents of Unit 16B.
Unit 16	Brown Bear	No Federal subsistence priority.
Unit 16A	Moose	No Federal subsistence priority.
Unit 16B	Moose	Residents of Unit 16B.
Unit 16	Sheep	No Federal subsistence priority.
Unit 16	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 16	Grouse (Spruce and Ruffed)	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22 and 23.
Unit 16	Ptarmigan (Rock, Willow and White-tailed).	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22 and 23.
Unit 17	Beaver	Residents of Units 9A, 9B, 9C, 9E, and 17.
Unit 17A and that portion of 17B draining into Nuyakuk Lake and Tikchik Lake.	Black Bear	Residents of Units 9A and B, 17, Akiak, and Akiachak.
Unit 17, remainder	Black Bear	Residents of Units 9A and B, and 17.
Unit 17A, those portions north and west of a line beginning from the Unit 18 boundary at the northwestern end of Nenevok Lake, to the southern point of upper Togiak Lake, and northeast towards the northern point of Nuyakuk Lake to the Unit 17A boundary.	Brown Bear	Residents of Unit 17, Akiak, Akiachak, Goodnews Bay, Kwethluk, and Platinum.

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Area	Species	Determination
Unit 17B, beginning at the Unit 17B boundary, those portions north and west of a line running from the southern point of upper Togiak Lake, northeast to the northern point of Nuyakuk Lake, and northeast to the point where the Unit 17 boundary intersects the Shotgun Hills.	Brown Bear	Residents of Unit 17 and Kwethluk.
Unit 17A, remainder	Brown Bear	Residents of Unit 17, Akiak, Akiachak, Goodnews Bay, and Platinum.
Unit 17B, that portion draining into Nuyakuk Lake and Tikchik Lake.	Brown Bear	Residents of Unit 17, Akiak and Akiachak.
Unit 17B, remainder, and Unit 17C	Brown Bear	Residents of Unit 17.
Unit 17A, that portion west of the Izavieknik River, Upper Togiak Lake, Togiak Lake, and the main course of the Togiak River.	Caribou	Residents of Units 9B, 17, Eek, Goodnews Bay, Lime Village, Napakiak, Platinum, Quinhagak, Stony River, and Tuntutuliak.
Unit 17A, that portion north of Togiak Lake that includes Izavieknik River drainages.	Caribou	Residents of Units 9B, 17, Akiak, Akiachak, Lime Village, Stony River, and Tuluksak.
Units 17A and 17B, those portions north and west of a line beginning from the Unit 18 boundary at the northwestern end of Nenevok Lake, to the southern point of upper Togiak Lake, and northeast to the northern point of Nuyakuk Lake, northeast to the point where the Unit 17 boundary intersects the Shotgun Hills.	Caribou	Residents of Units 9B, 17, Kwethluk, Lime Village, and Stony River.
Unit 17B, that portion of Togiak National Wildlife Refuge within Unit 17B.	Caribou	Residents of Units 9B, 17, Akiachak, Akiak, Bethel, Eek, Goodnews Bay, Lime Village, Napakiak, Platinum, Quinhagak, Stony River, Tuluksak, and Tuntutuliak.
Unit 17, remainder	Caribou	Residents of Units 9B, 9C, 9E, 17, Lime Village, and Stony River.
Unit 17A, those portions north and west of a line beginning from the Unit 18 boundary at the northwestern end of Nenevok Lake, to the southern point of upper Togiak Lake, and to the Unit 17A boundary to the northeast towards the northern point of Nuyakuk Lake and northeast towards the northern point of Nuyakuk Lake to the Unit 17A boundary.	Moose	Residents of Unit 17, Goodnews Bay, Kwethluk, and Platinum.
Unit 17A, that portion north of Togiak Lake that includes Izavieknik River drainages.	Moose	Residents of Unit 17, Akiak, Akiachak, Goodnews Bay, and Platinum.
Unit 17A, remainder	Moose	Residents of Unit 17, Goodnews Bay and Platinum.
Units 17B, beginning at the Unit 17B boundary, those portions north and west of a line running from the southern point of upper Togiak Lake, northeast to the northern point of Nuyakuk Lake, and northeast to the point where the Unit 17 boundary intersects the Shotgun Hills.	Moose	Residents of Unit 17, Akiak, Akiachak, Goodnews Bay, Levelock, Nondalton, and Platinum.
Unit 17B, that portion within the Togiak National Wildlife Refuge	Moose	Residents of Unit 17, Akiak, Akiachak, Goodnews Baym, Levelock, Nondalton, and Platinum.
Unit 17B, remainder and Unit 17C	Moose	Residents of Unit 17, Nondalton, Levelock, Goodnews Bay, and Platinum.
Unit 17	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 18	Black Bear	Residents of Unit 18, Unit 19A living downstream of the Holokuk River, Holy Cross, Stebbins, St. Michael, Twin Hills, and Togiak.
Unit 18	Brown Bear	Residents of Akiachak, Akiak, Eek, Goodnews Bay, Kwethluk, Mountain Village, Napaskiak, Platinum, Quinhagak, St. Marys, and Tuluksak.
Unit 18	Caribou	Residents of Unit 18, Lower Kalskag, Manokotak, Stebbins, St. Michael, Togiak, Twin Hills, and Upper Kalskag.
Unit 18, that portion of the Yukon River drainage upstream of Russian Mission and that portion of the Kuskokwim River drainage upstream of, but not including, the Tuluksak River drainage.	Moose	Residents of Unit 18, Upper Kalskag, Lower Kalskag, Aniak, and Chuathbaluk.
Unit 18, that portion north of a line from Cape Romanzof to Kusilvak Mountain to Mountain Village, and all drainages north of the Yukon River downstream from Marshall.	Moose	Residents of Unit 18, Lower Kalskag, St. Michael, Stebbins, and Upper Kalskag.
Unit 18, remainder	Moose	Residents of Unit 18, Lower Kalskag, and Upper Kalskag.
Unit 18	Musk Ox	No Federal subsistence priority.
Unit 18	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 19C and Unit 19D	Bison	No Federal subsistence priority.
Unit 19A and Unit 19B	Brown Bear	Residents of Units 18 and 19 within the Kuskokwim River drainage upstream from, and including, the Johnson River.
Unit 19C	Brown Bear	No Federal subsistence priority.
Unit 19D	Brown Bear	Residents of Units 19A and D, Tuluksak, and Lower Kalskag.
Unit 19A and Unit 19B	Caribou	Residents of Units 19A and 19B, Unit 18 within the Kuskokwim River drainage upstream from, and including, the Johnson River, and residents of St. Marys, Marshall, Pilot Station, and Russian Mission.
Unit 19C	Caribou	Residents of Unit 19C, Lime Village, McGrath, Nikolai, and Telida.
Unit 19D	Caribou	Residents of Unit 19D, Lime Village, Sleetmute, and Stony River.
Unit 19A and Unit 9B	Moose	Residents of Unit 18 within Kuskokwim River drainage upstream from and including the Johnson River, and residents of Unit 19.
Unit 19B, west of the Kogrukluk River	Moose	Residents of Eek and Quinhagak.

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Area	Species	Determination
Unit 19C	Moose	Residents of Unit 19.
Unit 19D	Moose	Residents of Unit 19 and Lake Minchumina.
Unit 19	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 20D	Bison	No Federal subsistence priority.
Unit 20F	Black Bear	Residents of Unit 20F, Stevens Village, and Manley Hot Springs.
Unit 20E	Brown Bear	Residents of Unit 12 and Dot Lake.
Unit 20F	Brown Bear	Residents of Unit 20F, Stevens Village, and Manley Hot Springs.
Unit 20A	Caribou	Residents of Cantwell, Nenana, and those domiciled between mileposts 216 and 239 of the Parks Highway, excluding residents of households of the Denali National Park Headquarters.
Unit 20B	Caribou	Residents of Unit 20B, Nenana, and Tanana.
Unit 20C	Caribou	Residents of Unit 20C living east of the Teklanika River, residents of Cantwell, Lake Minchumina, Manley Hot Springs, Minto, Nenana, Nikolai, Tanana, Telida, and those domiciled between mileposts 216 and 239 of the Parks Highway and between mileposts 300 and 309, excluding residents of households of the Denali National Park Headquarters.
Unit 20D and Unit 20E	Caribou	Residents of Units 20D, 20E, 20F, 25, 12 (north of the Wrangell-St. Elias National Park and Preserve), Eureka, Livengood, Manley, and Minto.
Unit 20F	Caribou	Residents of Units 20F and 25D and Manley Hot Springs.
Unit 20A	Moose	Residents of Cantwell, Minto, Nenana, McKinley Village, and the area along the Parks Highway between mileposts 216 and 239, excluding residents of households of the Denali National Park Headquarters.
Unit 20B, Minto Flats Management Area	Moose	Residents of Minto and Nenana.
Unit 20B, remainder	Moose	Residents of Unit 20B, Nenana, and Tanana.
Unit 20C	Moose	Residents of Unit 20C (except that portion within Denali National Park and Preserve and that portion east of the Teklanika River), Cantwell, Manley Hot Springs, Minto, Nenana, those domiciled between mileposts 300 and 309 of the Parks Highway, Nikolai, Tanana, Telida, McKinley Village, and the area along the Parks Highway between mileposts 216 and 239, excluding residents of households of the Denali National Park Headquarters.
Unit 20D	Moose	Residents of Unit 20D and Tanacross.
Unit 20E	Moose	Residents of Unit 20E, Unit 12 north of the Wrangell-St. Elias National Preserve, Circle, Central, Dot Lake, Healy Lake, and Mentasta Lake.
Unit 20F	Moose	Residents of Unit 20F, Manley Hot Springs, Minto, and Stevens Village.
Unit 20E	Sheep	Residents of Units 20E, 25B, 25C, 25D, and Dot Lake, Healy Lake, Northway, Tanacross, Tetlin, and Tok.
Unit 20F	Wolf	Residents of Unit 20F, Stevens Village, and Manley Hot Springs.
Unit 20, remainder	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 20D	Grouse, (Spruce, Ruffed and Sharp-tailed).	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22, and 23.
Unit 20D	Ptarmigan (Rock and Willow)	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22, and 23.
Unit 21	Brown Bear	Residents of Units 21 and 23.
Unit 21A	Caribou	Residents of Units 21A, 21D, 21E, Aniak, Chuathbaluk, Crooked Creek, McGrath, and Takotna.
Unit 21B and Unit 21C	Caribou	Residents of Units 21B, 21C, 21D, and Tanana.
Unit 21D	Caribou	Residents of Units 21B, 21C, 21D, and Huslia.
Unit 21E	Caribou	Residents of Units 21A, 21E, Aniak, Chuathbaluk, Crooked Creek, McGrath, and Takotna.
Unit 21A	Moose	Residents of Units 21A, 21E, Takotna, McGrath, Aniak, and Crooked Creek.
Unit 21B and Unit 21C	Moose	Residents of Units 21B, 21C, Tanana, Ruby, and Galena.
Unit 21D	Moose	Residents of Units 21D, Huslia, and Ruby.
Unit 21E, south of a line beginning at the western boundary of Unit 21E near the mouth of Paimiut Slough, extending easterly along the south bank of Paimiut Slough to Upper High Bank, and southeasterly in the direction of Molybdenum Mountain to the juncture of Units 19A, 21A, and 21E.	Moose	Residents of Unit 21E, Aniak, Chuathbaluk, Kalskag, Lower Kalskag, and Russian Mission.
Unit 21E remainder	Moose	Residents of Unit 21E and Russian Mission.
Unit 21	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 22A	Black Bear	Residents of Unit 22A and Koyuk.
Unit 22B	Black Bear	Residents of Unit 22B.
Unit 22C, Unit 22D, and Unit 22E	Black Bear	No Federal subsistence priority.
Unit 22	Brown Bear	Residents of Unit 22.

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Area	Species	Determination
Unit 22A	Caribou	Residents of Units 21D west of the Koyukuk and Yukon Rivers, 22 (except residents of St. Lawrence Island), 23, 24, Kotlik, Emmonak, Hooper Bay, Scammon Bay, Chevak, Marshall, Mountain Village, Pilot Station, Pitka's Point, Russian Mission, St. Marys, Nunam Iqua, and Alakanuk.
Unit 22, remainder	Caribou	Residents of Units 21D west of the Koyukuk and Yukon Rivers, 22 (excluding residents of St. Lawrence Island), 23, and 24.
Unit 22	Moose	Residents of Unit 22.
Unit 22A	Musk Ox	All rural residents.
Unit 22B, west of the Darby Mountains	Musk Ox	Residents of Units 22B and 22C.
Unit 22B, remainder	Musk Ox	Residents of Unit 22B.
Unit 22C	Musk Ox	Residents of Unit 22C.
Unit 22D	Musk Ox	Residents of Units 22B, 22C, 22D, and 22E (excluding St. Lawrence Island).
Unit 22E	Musk Ox	Residents of Unit 22E (excluding Little Diomede Island).
Unit 22	Wolf	Residents of Units 23, 22, 21D north and west of the Yukon River, and Kotlik.
Unit 22	Grouse (Spruce)	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22, and 23.
Unit 22	Ptarmigan (Rock and Willow)	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22, and 23.
Unit 23	Black Bear	Residents of Unit 23, Alatna, Allakaket, Bettles, Evansville, Galena, Hughes, Huslia, and Koyukuk.
Unit 23	Brown Bear	Residents of Units 21 and 23.
Unit 23	Caribou	Residents of Units 21D west of the Koyukuk and Yukon Rivers, Galena, 22, 23, 24 including residents of Wiseman but not including other residents of the Dalton Highway Corridor Management Area, and 26A.
Unit 23	Moose	Residents of Unit 23.
Unit 23, south of Kotzebue Sound and west of and including the Buckland River drainage.	Musk Ox	Residents of Unit 23 south of Kotzebue Sound and west of and including the Buckland River drainage.
Unit 23, remainder	Musk Ox	Residents of Unit 23 east and north of the Buckland River drainage.
Unit 23	Sheep	Residents of Point Lay and Unit 23 north of the Arctic Circle.
Unit 23	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 23	Grouse (Spruce and Ruffed)	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22, and 23.
Unit 23	Ptarmigan (Rock, Willow and White-tailed).	Residents of Units 11, 13, Chickaloon, 15, 16, 20D, 22, and 23.
Unit 24, that portion south of Caribou Mountain, and within the public lands composing or immediately adjacent to the Dalton Highway Corridor Management Area.	Black Bear	Residents of Stevens Village, Unit 24, and Wiseman, but not including any other residents of the Dalton Highway Corridor Management Area.
Unit 24, remainder	Black Bear	Residents of Unit 24 and Wiseman, but not including any other residents of the Dalton Highway Corridor Management Area.
Unit 24, that portion south of Caribou Mountain, and within the public lands composing or immediately adjacent to the Dalton Highway Corridor Management Area.	Brown Bear	Residents of Stevens Village and Unit 24.
Unit 24, remainder	Brown Bear	Residents of Unit 24.
Unit 24	Caribou	Residents of Unit 24, Galena, Kobuk, Koyukuk, Stevens Village, and Tanana.
Unit 24	Moose	Residents of Unit 24, Koyukuk, and Galena.
Unit 24	Sheep	Residents of Unit 24 residing north of the Arctic Circle, Allakaket, Alatna, Hughes, and Huslia.
Unit 24	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 1626.
Unit 25D	Black Bear	Residents of Unit 25D.
Unit 25D	Brown Bear	Residents of Unit 25D.
Unit 25, remainder	Brown Bear	Residents of Unit 25 and Eagle.
Unit 25A	Caribou	Residents of Units 24A and 25.
Unit 25B and Unit 25C	Caribou	Residents of Units 12 (north of Wrangell-St. Elias National Preserve), 20D, 20E, 20F, and 25, and Eureka, Livengood, Manley, and Minto.
Unit 25D	Caribou	Residents of Units 20F and 25D and Manley Hot Springs.
Unit 25A	Moose	Residents of Units 25A and 25D.
Unit 25B and Unit 25C	Moose	Residents of Units 20D, 20E, 25B, 25C, 25D, Tok and Livengood.
Unit 25D, west	Moose	Residents of Unit 25D West.
Unit 25D, remainder	Moose	Residents of remainder of Unit 25.
Unit 25A	Sheep	Residents of Arctic Village, Chalkyitsik, Fort Yukon, Kaktovik, and Venetie.
Unit 25B and Unit 25C	Sheep	Residents of Units 20E, 25B, 25C, and 25D.
Unit 25D	Wolf	Residents of Unit 25D.
Unit 25, remainder	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.
Unit 26	Brown Bear	Residents of Unit 26 (excluding the Prudhoe Bay-Deadhorse Industrial Complex), Anaktuvuk Pass, and Point Hope.
Unit 26A and C	Caribou	Residents of Unit 26, Anaktuvuk Pass, and Point Hope.
Unit 26B	Caribou	Residents of Unit 26, Anaktuvuk Pass, Point Hope, and Unit 24 within the Dalton Highway Corridor Management Area.
Unit 26	Moose	Residents of Unit 26 (excluding the Prudhoe Bay-Deadhorse Industrial Complex), Point Hope, and Anaktuvuk Pass.
Unit 26A	Musk Ox	Residents of Anaktuvuk Pass, Atqasuk, Barrow, Nuiqsut, Point Hope, Point Lay, and Wainwright.

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Area	Species	Determination
Unit 26B	Musk Ox	Residents of Anaktuvuk Pass, Nuiqsut, and Kaktovik.
Unit 26C	Musk Ox	Residents of Kaktovik.
Unit 26A	Sheep	Residents of Unit 26, Anaktuvuk Pass, and Point Hope.
Unit 26B	Sheep	Residents of Unit 26, Anaktuvuk Pass, Point Hope, and Wiseman.
Unit 26C	Sheep	Residents of Unit 26, Anaktuvuk Pass, Arctic Village, Chalkyitsik, Fort Yukon, Point Hope, and Venetie.
Unit 26	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11–13, Chickaloon, and 16–26.

* * * * *

Subpart D—Subsistence Taking of Fish and Wildlife

■ 3. Amend § __.25 by:
■ a. In paragraph (a), revising the definition of ''Hare or hares'';
■ b. Adding paragraph (c)(5); and
■ c. Revising paragraph (e).

The revisions and addition read as follows:

§ __.25 Subsistence taking of fish, wildlife, and shellfish: general regulations.

(a) * * *

Hare or hares collectively refers to all species of hares (commonly called rabbits) in Alaska and includes snowshoe hare and tundra or Alaska hare.

* * * * *

(c) * * *

(5) Fish, wildlife, or shellfish taken by a participant in a community harvest system counts toward both the community harvest limit or quota for that species as well as individual harvest limits, Federal or State, for each participant in that community harvest system; however, the take does not count toward individual harvest limits, Federal or State, of any non-participant.

(i) Fish, wildlife, or shellfish taken by someone who is not a participant in a community harvest system does not count toward any community harvest limit or quota.

(ii) For the purposes of this provision, all residents of the community are deemed participants in the community harvest unless the Board-approved framework requires registration as a prerequisite to harvesting or receiving any fish, wildlife, or shellfish pursuant to that community harvest, in which case only those who register are deemed participants in that community harvest.

* * * * *

(e) *Hunting by designated harvest permit.* If you are a federally qualified subsistence user (recipient), you may designate another federally qualified subsistence user to take deer, moose, and caribou, and in Units 1–5, goats, on your behalf unless unit-specific regulations in § __.26 preclude or modify the use of the designated hunter system or allow the harvest of additional species by a designated hunter. The designated hunter must obtain a designated hunter permit and must return a completed harvest report. The designated hunter may hunt for any number of recipients but may have no more than two harvest limits in his/her possession at any one time except for goats, where designated hunters may have no more than one harvest limit in possession at any one time, and unless otherwise specified in unit-specific regulations in § __.26.

* * * * *

■ 4. Amend § __.26 by revising paragraphs (e), (j)(1), and (n) to read as follows:

§ 100.26 Subsistence taking of wildlife.

* * * * *

(e) *Possession and transportation of wildlife.* Except as specified in paragraph (f)(1) of this section, or as otherwise provided, you may not take a species of wildlife in any Unit, or portion of a Unit, if your total take of that species already obtained anywhere in the State under Federal and State regulations equals or exceeds the harvest limit in that Unit.

* * * * *

(j) * * * (1) Sealing requirements for brown bear taken apply in all Units, except as specified in this paragraph (j). Sealing requirements for black bears of all color phases taken apply in Units 1–7, 13–17, and 20.

* * * * *

(n) *Unit regulations.* You may take for subsistence unclassified wildlife, all squirrel species and marmots in all Units, without harvest limits, for the period of July 1 June 30. Unit-specific restrictions or allowances for subsistence taking of wildlife are identified at paragraphs (n)(1) through (26) of this section.

(1) *Unit 1.* Unit 1 consists of all mainland drainages from Dixon Entrance to Cape Fairweather, and those islands east of the center line of Clarence Strait from Dixon Entrance to Caamano Point, and all islands in Stephens Passage and Lynn Canal north of Taku Inlet:

(i) Unit 1A consists of all drainages south of the latitude of Lemesurier Point including all drainages into Behm Canal, excluding all drainages of Ernest Sound.

(ii) Unit 1B consists of all drainages between the latitude of Lemesurier Point and the latitude of Cape Fanshaw including all drainages of Ernest Sound and Farragut Bay, and including the islands east of the center lines of Frederick Sound, Dry Strait (between Sergief and Kadin Islands), Eastern Passage, Blake Channel (excluding Blake Island), Ernest Sound, and Seward Passage.

(iii) Unit 1C consists of that portion of Unit 1 draining into Stephens Passage and Lynn Canal north of Cape Fanshaw and south of the latitude of Eldred Rock including Berners Bay, Sullivan Island, and all mainland portions north of Chichagof Island and south of the latitude of Eldred Rock, excluding drainages into Farragut Bay.

(iv) Unit 1D consists of that portion of Unit 1 north of the latitude of Eldred Rock, excluding Sullivan Island and the drainages of Berners Bay.

(v) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public lands:

(A) Public lands within Glacier Bay National Park are closed to all taking of wildlife for subsistence uses;

(B) Unit 1A—in the Hyder area, the Salmon River drainage downstream from the Riverside Mine, excluding the Thumb Creek drainage, is closed to the taking of bear;

(C) Unit 1B—the Anan Creek drainage within 1 mile of Anan Creek downstream from the mouth of Anan Lake, including the area within a 1-mile radius from the mouth of Anan Creek Lagoon, is closed to the taking of bear; and

(D) Unit 1C:

(*1*) You may not hunt within one-fourth mile of Mendenhall Lake, the U.S. Forest Service Mendenhall Glacier Visitor's Center, and the Center's parking area; and

(*2*) You may not take mountain goat in the area of Mt. Bullard bounded by the Mendenhall Glacier, Nugget Creek from its mouth to its confluence with Goat Creek, and a line from the mouth of Goat Creek north to the Mendenhall Glacier.

(vi) You may not trap furbearers for subsistence uses in Unit 1C, Juneau area, on the following public lands:

(A) A strip within one-quarter mile of the mainland coast between the end of Thane Road and the end of Glacier Highway at Echo Cove;

(B) That area of the Mendenhall Valley bounded on the south by the Glacier Highway, on the west by the Mendenhall Loop Road and Montana Creek Road and Spur Road to Mendenhall Lake, on the north by Mendenhall Lake, and on the east by the Mendenhall Loop Road and Forest Service Glacier Spur Road to the Forest Service Visitor Center;

(C) That area within the U.S. Forest Service Mendenhall Glacier Recreation Area; and

(D) A strip within one-quarter mile of the following trails as designated on U.S. Geological Survey maps: Herbert Glacier Trail, Windfall Lake Trail, Peterson Lake Trail, Spaulding Meadows Trail (including the loop trail), Nugget Creek Trail, Outer Point Trail, Dan Moller Trail, Perseverance Trail, Granite Creek Trail, Mt. Roberts Trail and Nelson Water Supply Trail, Sheep Creek Trail, and Point Bishop Trail.

(vii) Unit-specific regulations:

(A) You may hunt black bear with bait in Units 1A, 1B, and 1D between April 15 and June 15.

(B) You may not shoot ungulates, bear, wolves, or wolverine from a boat, unless you are certified as disabled.

(C) Coyotes taken incidentally with a trap or snare during an open Federal trapping season for wolf, wolverine, or beaver may be legally retained.

(D) A firearm may be used to take beaver under a trapping license during an open beaver season, except on National Park Service lands.

TABLE 1 TO PARAGRAPH (n)(1)

Harvest limits	Open season
Hunting	
Black Bear: 2 bears, no more than one may be a blue or glacier bear	Sep. 1–June 30.
Brown Bear: 1 bear every 4 regulatory years by State registration permit only	Sep. 15–Dec. 31. Mar. 15–May 31.
Deer:	
Unit 1A—4 antlered deer	Aug. 1–Dec. 31.
Unit 1B—2 antlered deer	Aug. 1–Dec. 31.
Unit 1C—4 deer; however, female deer may be taken only Sep. 15–Dec. 31	Aug. 1–Dec. 31.
Elk: 1 elk by Federal registration permit	July 1–June 30.
Successful hunters must send a photo of their elk antlers to ADF&G and a 5-inch section of the lower jaw with front teeth	
Goat:	
Unit 1A, Revillagigedo Island only	No open season.
Unit 1B, that portion north of LeConte Bay—1 goat by State registration permit only; the taking of kids or nannies accompanied by kids is prohibited.	Aug. 1–Dec. 31.
Unit 1A and Unit 1B, that portion on the Cleveland Peninsula south of the divide between Yes Bay and Santa Anna Inlet.	No open season.
Unit 1A and Unit 1B, remainder—2 goats; a State registration permit will be required for the taking of the first goat and a Federal registration permit for the taking of a second goat. The taking of kids or nannies accompanied by kids is prohibited.	Aug. 1–Dec. 31.
Unit 1C, that portion draining into Lynn Canal and Stephens Passage between Antler River and Eagle Glacier and River, and all drainages of the Chilkat Range south of the Endicott River—1 goat by State registration permit only.	Oct. 1–Nov. 30.
Unit 1C, that portion draining into Stephens Passage and Taku Inlet between Eagle Glacier and River and Taku Glacier.	No open season.
Unit 1C, remainder—1 goat by State registration permit only	Aug. 1–Nov. 30.
Unit 1D, that portion lying north of the Katzehin River and northeast of the Haines highway—1 goat by State registration permit only.	Sep. 15–Nov. 30.
Unit 1D, that portion lying between Taiya Inlet and River and the White Pass and Yukon Railroad	No open season.
Unit 1D, remainder—1 goat by State registration permit only	Aug. 1–Dec. 31.
Moose:	
Unit 1A—1 antlered bull by Federal registration permit	Sep. 5–Oct. 15.
Unit 1B—1 antlered bull with spike-fork or 50-inch antlers or 3 or more brow tines on one side, or antlers with 2 brow tines on both sides, by State registration permit only.	Sep. 15–Oct. 15.
Unit 1C, that portion south of Point Hobart including all Port Houghton drainages—1 antlered bull with spike-fork or 50-inch antlers or 3 or more brow tines on one side, or antlers with 2 brow tines on both sides, by State registration permit only.	Sep. 15–Oct. 15.
Unit 1C, remainder, excluding drainages of Berners Bay—1 bull by State registration permit only	Sep. 15–Oct. 15.
Unit 1C, Berners Bay—1 bull by drawing permit	Sep.15–Oct. 15 (will be announced).
Only one moose permit may be issued per household. A household receiving a State permit for Berners Bay drainages moose may not receive a Federal permit. The annual harvest quota will be announced by the USDA Forest Service, Juneau office, in consultation with ADF&G. The Federal harvest allocation will be 25% (rounded up to the next whole number) of bull moose permits	
Unit 1D	No open season.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black, and Silver Phases): 2 foxes	Nov. 1–Feb. 15.
Hare (Snowshoe): 5 hares per day	Sep. 1–Apr. 30.
Lynx: 2 lynx	Dec. 1–Feb. 15.
Wolf:	

TABLE 1 TO PARAGRAPH (n)(1)—Continued

Harvest limits	Open season
Units 1A and 1B, south of Bradfield Canal and the east fork of the Bradfield River—5 wolves	Aug. 1–May 31.
Units 1B, remainder, 1C, and 1D—5 wolves	Aug. 1–Apr. 30.
Wolverine: 1 wolverine	Nov. 10–Feb. 15.
Grouse (Spruce, Blue, and Ruffed): 5 per day, 10 in possession	Aug. 1–May 15.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 1–May 15.
Trapping	
Beaver: Unit 1—No limit	Nov. 10–May 15.
Coyote: No limit	Dec. 1–Feb. 15.
Fox, Red (including Cross, Black, and Silver Phases): No limit	Dec. 1–Feb. 15.
Lynx: No limit	Dec. 1–Feb. 15.
Marten: No limit	Dec. 1–Feb. 15.
Mink and Weasel: No limit.	
Muskrat: No limit	Dec. 1–Feb. 15.
Otter: No limit	Dec. 1–Feb. 15.
Wolf: No limit	Nov. 1–Apr. 30.
Wolverine: No limit	Nov. 10–Mar. 1.

(2) *Unit 2.* Unit 2 consists of Prince of Wales Island and all islands west of the center lines of Clarence Strait and Kashevarof Passage, south and east of the center lines of Sumner Strait, and east of the longitude of the westernmost point on Warren Island.

(i) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15.

(B) You may not shoot ungulates, bear, wolves, or wolverine from a boat, unless you are certified as disabled.

(C) Coyotes taken incidentally with a trap or snare during an open Federal trapping season for wolf, wolverine, or beaver may be legally retained.

(D) A firearm may be used to take beaver under a trapping license during an open beaver season, except on National Park Service lands.

(ii) [Reserved]

TABLE 2 TO PARAGRAPH (n)(2)

Harvest limits	Open season
Hunting	
Black Bear: 2 bears, no more than one may be a blue or glacier bear	Sep. 1–June 30.
Deer:	
5 deer; however, no more than one may be a female deer. Female deer may be taken only during the period Oct. 15–Jan. 31. Harvest ticket number five must be used when recording the harvest of a female deer, but may be used for recording the harvest of a male deer. Harvest tickets must be used in order except when recording a female deer on tag number five.	July 24–Jan. 31.
The Federal public lands on Prince of Wales Island, excluding the southeastern portion (lands south of the West Arm of Cholmondeley Sound draining into Cholmondeley Sound or draining eastward into Clarence Strait), are closed to hunting of deer Aug. 1–15, except by federally qualified subsistence users hunting under these regulations.	
Non-federally qualified users may only harvest up to 2 male deer on Federal public lands in Unit 2.	
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Elk: 1 elk by Federal registration permit	Jul 1–Jun 30.
Successful hunters must send a photo of their elk antlers to ADF&G and a 5-inch section of the lower jaw with front teeth.	
Fox, Red (including Cross, Black, and Silver Phases): 2 foxes	Nov. 1–Feb. 15.
Hare (Snowshoe): 5 hares per day	Sep. 1–Apr. 30.
Lynx: 2 lynx	Dec. 1–Feb. 15.
Wolf: No limit. All wolves taken will be sequentially numbered, marked with the date and location recorded by the hunter for each wolf, and all hides must be sealed within 15 days of take.	Sep. 1–Mar. 31.
Wolverine: 1 wolverine	Nov. 10–Feb. 15.
Grouse (Spruce and Ruffed): 5 per day, 10 in possession	Aug. 1–May 15.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 1–May 15.
Trapping	
Beaver: No limit	Nov. 10–May 15.
Coyote: No limit	Dec. 1–Feb. 15.
Fox, Red (including Cross, Black, and Silver Phases): No limit	Dec. 1–Feb. 15.
Lynx: No limit	Dec. 1–Feb. 15.
Marten: No limit	Dec. 1–Feb. 15.
Mink and Weasel: No limit	Dec. 1–Feb. 15.
Muskrat: No limit	Dec. 1–Feb. 15.
Otter: No limit	Dec. 1–Feb. 15.
Wolf: No limit. All wolves taken will be sequentially numbered, marked with the date and location recorded by the trapper for each wolf, and all hides must be sealed within 15 days of take.	Nov. 15–Mar. 31.

TABLE 2 TO PARAGRAPH (n)(2)—Continued

Harvest limits	Open season
Wolverine: No limit	Nov. 10–Mar. 1.

(3) *Unit 3.* (i) Unit 3 consists of all islands west of Unit 1B, north of Unit 2, south of the center line of Frederick Sound, and east of the center line of Chatham Strait including Coronation, Kuiu, Kupreanof, Mitkof, Zarembo, Kashevaroff, Woronkofski, Etolin, Wrangell, and Deer Islands.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public lands:

(A) In the Petersburg vicinity, you may not take ungulates, bear, wolves, and wolverine along a strip one-fourth mile wide on each side of the Mitkof Highway from Milepost 0 to Crystal Lake campground;

(B) You may not take black bears in the Petersburg Creek drainage on Kupreanof Island; and

(C) You may not hunt in the Blind Slough draining into Wrangell Narrows and a strip one-fourth-mile wide on each side of Blind Slough, from the hunting closure markers at the southernmost portion of Blind Island to the hunting closure markers 1 mile south of the Blind Slough bridge.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15.

(B) You may not shoot ungulates, bear, wolves, or wolverine from a boat, unless you are certified as disabled.

(C) Coyotes taken incidentally with a trap or snare during an open Federal trapping season for wolf, wolverine, or beaver may be legally retained.

(D) A firearm may be used to take beaver under a trapping license during an open beaver season, except on National Park Service lands.

TABLE 3 TO PARAGRAPH (n)(3)

Harvest limits	Open season
Hunting	
Black Bear: 2 bears, no more than one may be a blue or glacier bear	Sep. 1–June 30.
Deer:	
Unit 3, Mitkof, Woewodski, and Butterworth Islands and that portion of Kupreanof Island on the Lindenberg Peninsula east of the Portage Bay-Duncan Canal Portage—1 buck.	Oct. 1–Nov. 7.
Unit 3, remainder—2 bucks	Aug. 1–Nov. 30. Dec. 1–31, season to be announced.
Elk:	
Unit 3, Etolin, Zarembo, Bushy, Shrubby, and Kashevarof Islands	No open season.
Unit 3 remainder—1 elk by Federal registration permit	July 1–June 30.
Successful hunters must send a photo of their elk antlers to ADF&G and a 5-inch section of the lower jaw with front teeth.	
Moose: 1 antlered bull with spike-fork or 50-inch antlers or 3 or more brow tines on either antler, or antlers with 2 brow tines on both sides by State registration permit only.	Sep. 1–Oct. 15.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black, and Silver Phases): 2 foxes	Nov. 1–Feb. 15.
Hare (Snowshoe): 5 hares per day	Sep. 1–Apr. 30.
Lynx: 2 lynx	Dec. 1–Feb. 15.
Wolf: 5 wolves	Aug. 1–May 31.
Wolverine: 1 wolverine	Nov. 10–Feb. 15.
Grouse (Spruce, Blue, and Ruffed): 5 per day, 10 in possession	Aug. 1–May 15.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 1–May 15.
Trapping	
Beaver:	
Unit 3, Mitkof Island—No limit	Nov. 10–May 15.
Unit 3, except Mitkof Island—No limit	Nov. 10–May 15.
Coyote: No limit	Dec. 1–Feb. 15.
Fox, Red (including Cross, Black, and Silver Phases): No limit	Dec. 1–Feb. 15.
Lynx: No limit	Dec. 1–Feb. 15.
Marten:	
No limit (except on Kuiu Island)	Dec. 1–Feb. 15.
Kuiu Island portion of Unit 3. No limit	Dec. 1–31.
Mink and Weasel: No limit	Dec. 1–Feb. 15.
Muskrat: No limit	Dec. 1–Feb. 15.
Otter: No limit	Dec. 1–Feb. 15.
Wolf: No limit	Nov. 1–Apr. 30.
Wolverine: No limit	Nov. 10–Mar. 1.

(4) *Unit 4.* (i) Unit 4 consists of all islands south and west of Unit 1C and north of Unit 3 including Admiralty, Baranof, Chichagof, Yakobi, Inian, Lemesurier, and Pleasant Islands.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public lands:

(A) You may not take brown bears in the Seymour Canal Closed Area (Admiralty Island) including all drainages into northwestern Seymour Canal between Staunch Point and the southernmost tip of the unnamed peninsula separating Swan Cove and King Salmon Bay including Swan and Windfall Islands;

(B) You may not take brown bears in the Salt Lake Closed Area (Admiralty Island) including all lands within one-fourth mile of Salt Lake above Klutchman Rock at the head of Mitchell Bay;

(C) You may not take brown bears in the Port Althorp Closed Area (Chichagof Island), that area within the Port Althorp watershed south of a line from Point Lucan to Salt Chuck Point (Trap Rock); and

(D) You may not use any motorized land vehicle for brown bear hunting in the Northeast Chichagof Controlled Use Area (NECCUA) consisting of all portions of Unit 4 on Chichagof Island north of Tenakee Inlet and east of the drainage divide from the northwestern point of Gull Cove to Port Frederick Portage, including all drainages into Port Frederick and Mud Bay.

(iii) Unit-specific regulations:

(A) You may shoot ungulates from a boat. You may not shoot bear, wolves, or wolverine from a boat, unless you are certified as disabled.

(B) Five Federal registration permits will be issued by the Sitka or Hoonah District Ranger for the taking of brown bear for educational purposes associated with teaching customary and traditional subsistence harvest and use practices. Any bear taken under an educational permit does not count in an individual's one bear every 4 regulatory years limit.

(C) Coyotes taken incidentally with a trap or snare during an open Federal trapping season for wolf, wolverine, or beaver may be legally retained.

(D) A firearm may be used to take beaver under a trapping license during an open beaver season, except on National Park Service lands.

TABLE 4 TO PARAGRAPH (n)(4)

Harvest limits	Open season
Hunting	
Brown Bear:	
Unit 4, Chichagof Island south and west of a line that follows the crest of the island from Rock Point (58° N lat., 136°21′ W long.) to Rodgers Point (57°35′ N lat., 135°33′ W long.) including Yakobi and other adjacent islands; Baranof Island south and west of a line that follows the crest of the island from Nismeni Point (57°34′ N lat., 135°25′ W long.) to the entrance of Gut Bay (56°44′ N lat. 134°38′ W long.) including the drainages into Gut Bay and including Kruzof and other adjacent islands—1 bear every 4 regulatory years by State registration permit only.	Sep. 15–Dec. 31. Mar. 15–May 31.
Unit 4, remainder—1 bear every 4 regulatory years by State registration permit only	Sep. 15–Dec. 31. Mar. 15–May 20.
Deer: 6 deer; however, female deer may be taken only Sep. 15–Jan. 31	Aug. 1–Jan. 31.
Elk: 1 elk by Federal registration permit	July 1–June 30.
Successful hunters must send a photo of their elk antlers to ADF&G and a 5-inch section of the lower jaw with front teeth.	
Goat: 1 goat by State registration permit only	Aug. 1–Dec. 31.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black, and Silver Phases): 2 foxes	Nov. 1–Feb. 15.
Hare (Snowshoe): 5 hares per day	Sep. 1–Apr. 30.
Lynx: 2 lynx	Dec. 1–Feb. 15.
Wolf: 5 wolves	Aug. 1–Apr. 30.
Wolverine: 1 wolverine	Nov. 10–Feb. 15.
Grouse (Spruce, Blue, and Ruffed): 5 per day, 10 in possession	Aug. 1–May 15.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 1–May 15.
Trapping	
Beaver: No limit	Nov. 10–May 15.
Coyote: No limit	Dec. 1–Feb. 15.
Fox, Red (including Cross, Black, and Silver Phases): No limit	Dec. 1–Feb. 15.
Lynx: No limit	Dec. 1–Feb. 15.
Marten: No limit	Dec. 1–Feb. 15.
Mink and Weasel: No limit	Dec. 1–Feb. 15.
Muskrat: No limit	Dec. 1–Feb. 15.
Otter: No limit	Dec. 1–Feb. 15.
Wolf: No limit	Nov. 10–Apr. 30.
Wolverine: No limit	Nov. 10–Mar. 1.

(5) *Unit 5.* (i) Unit 5 consists of all Gulf of Alaska drainages and islands between Cape Fairweather and the center line of Icy Bay, including the Guyot Hills:

(A) Unit 5A consists of all drainages east of Yakutat Bay, Disenchantment Bay, and the eastern edge of Hubbard Glacier, and includes the islands of Yakutat and Disenchantment Bays; In Unit 5A, Nunatak Bench is defined as that area east of the Hubbard Glacier, north of Nunatak fiord, and north and east of the East Nunatak Glacier to the Canadian border.

(B) Unit 5B consists of the remainder of Unit 5.

(ii) You may not take wildlife for subsistence uses on public lands within Glacier Bay National Park.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15.

(B) You may not shoot ungulates, bear, wolves, or wolverine from a boat, unless you are certified as disabled.

(C) You may hunt brown bear in Unit 5 with a Federal registration permit in lieu of a State metal locking tag if you

have obtained a Federal registration permit prior to hunting.

(D) Coyotes taken incidentally with a trap or snare during an open Federal trapping season for wolf, wolverine, or beaver may be legally retained.

(E) A firearm may be used to take beaver under a trapping license during an open beaver season, except on National Park Service lands.

TABLE 5 TO PARAGRAPH (n)(5)

Harvest limits	Open season
Hunting	
Black Bear: 2 bears, no more than one may be a blue or glacier bear	Sep. 1–June 30.
Brown Bear: 1 bear by Federal registration permit only	Sep. 1–May 31.
Deer:	
Unit 5A—1 buck	Nov. 1–30.
Unit 5B	No open season.
Goat:	
Unit 5A—that area between the Hubbard Glacier and the West Nunatak Glacier on the north and east sides of Nunatak Fjord.	No open season.
Unit 5A, remainder—1 goat by Federal registration permit only	Aug. 1–Jan. 31.
Unit 5B—1 goat by Federal registration permit only	Aug. 1–Jan. 31.
Moose:	
Unit 5A, Nunatak Bench—1 moose by State registration permit only. The season will be closed when 5 moose have been taken from the Nunatak Bench.	Nov. 15–Feb. 15.
Unit 5A, except Nunatak Bench, west of the Dangerous River—1 bull by joint State/Federal registration permit only. From Oct. 8–21, public lands will be closed to taking of moose, except by residents of Unit 5A hunting under these regulations.	Oct. 8–Nov. 15.
Unit 5A, except Nunatak Bench, east of the Dangerous River—1 bull by joint State/Federal registration permit only. From Sep. 16–30, public lands will be closed to taking of moose, except by residents of Unit 5A hunting under these regulations.	Sep. 16–Nov. 15.
Unit 5B—1 bull by State registration permit only. The season will be closed when 25 bulls have been taken from the entirety of Unit 5B.	Sep. 1–Dec. 15.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 2 foxes	Nov. 1–Feb. 15.
Hare (Snowshoe): 5 hares per day	Sep. 1–Apr. 30.
Lynx: 2 lynx	Dec. 1–Feb. 15.
Wolf: 5 wolves	Aug. 1–Apr. 30.
Wolverine: 1 wolverine	Nov. 10–Feb. 15.
Grouse (Spruce and Ruffed): 5 per day, 10 in possession	Aug. 1–May 15.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 1–May 15.
Trapping	
Beaver: No limit	Nov. 10–May 15.
Coyote: No limit	Nov. 10–Feb. 15.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Feb. 15.
Lynx: No limit	Dec. 1–Feb. 15.
Marten: No limit	Nov. 10–Feb. 15.
Mink and Weasel: No limit	Nov. 10–Feb. 15.
Muskrat: No limit	Dec. 1–Feb. 15.
Otter: No limit	Nov. 10–Feb. 15.
Wolf: No limit	Nov. 10–Apr. 30.
Wolverine: No limit	Nov. 10–Mar. 1.

(6) *Unit 6.* (i) Unit 6 consists of all Gulf of Alaska and Prince William Sound drainages from the center line of Icy Bay (excluding the Guyot Hills) to Cape Fairfield including Kayak, Hinchinbrook, Montague, and adjacent islands, and Middleton Island, but excluding the Copper River drainage upstream from Miles Glacier, and excluding the Nellie Juan and Kings River drainages:

(A) Unit 6A consists of Gulf of Alaska drainages east of Palm Point near Katalla including Kanak, Wingham, and Kayak Islands;

(B) Unit 6B consists of Gulf of Alaska and Copper River Basin drainages west of Palm Point near Katalla, east of the west bank of the Copper River, and east of a line from Flag Point to Cottonwood Point;

(C) Unit 6C consists of drainages west of the west bank of the Copper River, and west of a line from Flag Point to Cottonwood Point, and drainages east of the east bank of Rude River and drainages into the eastern shore of Nelson Bay and Orca Inlet; and

(D) Unit 6D consists of the remainder of Unit 6.

(ii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15. In addition, you may use bait in Unit 6D between June 16 and June 30. The harvest quota in Unit 6D is 20 bears taken with bait between June 16 and June 30.

(B) You may take coyotes in Units 6B and 6C with the aid of artificial lights.

(C) One permit will be issued by the Cordova District Ranger to the Native Village of Eyak to take one moose from Federal lands in Unit 6B or 6C for their annual Memorial/Sobriety Day potlatch.

(D) A federally qualified subsistence user (recipient) who is either blind, 65 years of age or older, at least 70 percent disabled, or temporarily disabled may designate another federally qualified subsistence user to take any moose, deer, black bear, and beaver on his or her behalf in Unit 6 and goat in Unit 6D. The designated hunter must obtain a

designated hunter permit and must return a completed harvest report. The designated hunter may hunt for any number of recipients but may have no more than one harvest limit in his or her possession at any one time.

(E) A hunter younger than 10 years old at the start of the hunt may not be issued a Federal subsistence permit to harvest black bear, deer, goat, moose, wolf, and wolverine.

(F) A hunter younger than 10 years old may harvest black bear, deer, goat, moose, wolf, and wolverine under the direct, immediate supervision of a licensed adult, at least 18 years old. The animal taken is counted against the adult's harvest limit. The adult is responsible for ensuring that all legal requirements are met.

(G) Up to five permits will be issued by the Cordova District Ranger to the Native Village of Chenega annually to harvest up to five deer total from Federal public lands in Unit 6D for their annual Old Chenega Memorial and other traditional memorial potlatch ceremonies. Permits will have effective dates of July 1–June 30.

(H) Up to five permits will be issued by the Cordova District Ranger to the Tatitlek IRA Council annually to harvest up to five deer total from Federal public lands in Unit 6D for their annual Cultural Heritage Week. Permits will have effective dates of July 1–June 30.

TABLE 6 TO PARAGRAPH (n)(6)

Harvest limits	Open season
Hunting	
Black Bear: 1 bear. In Unit 6D, a State registration permit is required	Sep. 1–June 30.
Deer:	
5 deer; however, antlerless deer may be taken only from Oct. 1–Jan. 31. Only 1 of the 5-deer harvest limit may be taken between Jan. 1–31.	Aug. 1–Jan. 31.
Goats:	
Unit 6A and B—1 goat by State registration permit only	Aug. 20–Jan. 31.
Unit 6C	No open season.
Unit 6D (subareas RG242, RG243, RG244, RG245, RG249, RG266, and RG252 only)—1 goat by Federal registration permit only. In each of the Unit 6D subareas, goat seasons will be closed by the Cordova District Ranger when harvest limits for that subarea are reached. Harvest quotas are as follows: RG242—2 goats, RG243—4 goats, RG244 and RG245 combined—2 goats, RG249—4 goats, RG266—4 goats, RG252—1 goat.	Aug. 20–Feb. 28.
Moose:	
Unit 6C—1 antlerless moose by Federal drawing permit only	Sep. 1–Oct. 31.
Permits for the portion of the antlerless moose quota not harvested in the Sep. 1–Oct. 31 hunt may be available for redistribution for a Nov. 1–Dec. 31 hunt.	
Unit 6C—1 bull by Federal drawing permit only	Sep. 1–Dec. 31.
In Unit 6C, only one moose permit may be issued per household. A household receiving a State permit for Unit 6C moose may not receive a Federal permit. The annual harvest quota will be announced by the U.S. Forest Service, Cordova Office, in consultation with ADF&G. The Federal harvest allocation will be 100% of the antlerless moose permits and 75% of the bull permits. Federal public lands are closed to the harvest of moose except by federally qualified users with a Federal permit for Unit 6C moose, Nov. 1–Dec. 31.	
Unit 6, remainder	No open season.
Beaver: 1 beaver per day, 1 in possession	May 1–Oct. 31.
Coyote:	
Unit 6A and D—2 coyotes	Sep. 1–Apr. 30.
Unit 6B and 6C—No limit	July 1–June 30.
Fox, Red (including Cross, Black and Silver Phases):	No open season.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 10–Jan. 31.
Wolf: 5 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce): 5 per day, 10 in possession	Aug. 1–May 15.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 1–May 15.
Trapping	
Beaver: No limit	Dec. 1–Apr. 30.
Coyote:	
Unit 6C, south of the Copper River Highway and east of the Heney Range—No limit	Nov. 10–Apr. 30.
Units 6A, 6B, 6C, remainder, and 6D—No limit	Nov. 10–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Feb. 28.
Marten: No limit	Nov. 10–Feb. 28.
Mink and Weasel: No limit	Nov. 10–Jan. 31.
Muskrat: No limit	Nov. 10–June 10.
Otter: No limit	Nov. 10–Mar. 31
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: No limit	Nov. 10–Feb. 28.

(7) *Unit 7.* (i) Unit 7 consists of Gulf of Alaska drainages between Gore Point and Cape Fairfield including the Nellie Juan and Kings River drainages, and including the Kenai River drainage upstream from the Russian River, the drainages into the south side of Turnagain Arm west of and including the Portage Creek drainage, and east of

150° W long., and all Kenai Peninsula drainages east of 150° W long., from Turnagain Arm to the Kenai River.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public lands:

(A) You may not take wildlife for subsistence uses in the Kenai Fjords National Park.

(B) You may not hunt in the Portage Glacier Closed Area in Unit 7, which consists of Portage Creek drainages between the Anchorage-Seward Railroad and Placer Creek in Bear Valley, Portage Lake, the mouth of Byron Creek, Glacier Creek, and Byron Glacier; however, you may hunt grouse, ptarmigan, hares, and squirrels with shotguns after September 1.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15, except in the drainages of Resurrection Creek and its tributaries.

(B) [Reserved]

TABLE 7 TO PARAGRAPH (n)(7)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Caribou:	
Unit 7, north of the Sterling Highway and west of the Seward Highway—1 caribou by Federal registration permit only. The Seward District Ranger will close the Federal season when 5 caribou are harvested by Federal registration permit.	Aug. 10–Dec. 31.
Unit 7, remainder	No open season.
Goat: 1 goat by Federal Drawing permit. Nannies accompanied by kids may not be taken	Aug. 10–Nov 14.
Moose:	
Unit 7, that portion draining into Kings Bay—Federal public lands are closed to the taking of moose except by residents of Chenega Bay and Tatitlek.	No open season.
Unit 7, remainder—1 antlered bull with spike-fork or 50-inch antlers or with 3 or more brow tines on either antler, by Federal registration permit only.	Aug. 20–Sep. 25.
Sheep: 1 ram with full curl horn or larger by Federal drawing permit	Aug. 10–Sep. 20.
Beaver: 1 beaver per day, 1 in possession	May 1–Oct. 10.
Coyote: No limit	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases):	No open season.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 10–Jan. 31.
Wolf:	
Unit 7, that portion within the Kenai National Wildlife Refuge—2 wolves	Aug. 10–Apr. 30.
Unit 7, remainder—5 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce): 10 per day, 20 in possession	Aug. 10–Mar. 31.
Grouse (Ruffed):	No open season.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Mar. 31.
Trapping	
Beaver: 20 beaver per season	Nov. 10–Mar. 31.
Coyote: No limit	Nov. 10–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Feb. 28.
Lynx: No limit	Jan. 1–31.
Marten: No limit	Nov. 10–Jan. 31.
Mink and Weasel: No limit	Nov. 10–Jan. 31.
Muskrat: No limit	Nov. 10–May 15.
Otter: No limit	Nov. 10–Feb. 28.
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: No limit	Nov. 10–Feb. 28.

(8) *Unit 8.* Unit 8 consists of all islands southeast of the centerline of Shelikof Strait including Kodiak, Afognak, Whale, Raspberry, Shuyak, Spruce, Marmot, Sitkalidak, Amook, Uganik, and Chirikof Islands, the Trinity Islands, the Semidi Islands, and other adjacent islands.

(i) Unit-specific regulations: If you have a trapping license, you may take beaver with a firearm in Unit 8 from Nov. 10 through Apr. 30.

(ii) [Reserved]

TABLE 8 TO PARAGRAPH (n)(8)

Harvest limits	Open season
Hunting	
Brown Bear: 1 bear by Federal registration permit only. Up to 2 permits may be issued in Akhiok; up to 1 permit may be issued in Karluk; up to 3 permits may be issued in Larsen Bay; up to 3 permits may be issued in Old Harbor; up to 2 permits may be issued in Ouzinkie; and up to 2 permits may be issued in Port Lions. Permits will be issued by the Kodiak Refuge Manager.	Dec. 1–Dec. 15. Apr. 1–May 15.
Deer: Unit 8, all lands within the Kodiak Archipelago within the Kodiak National Wildlife Refuge, including lands on Kodiak, Ban, Uganik, and Afognak Islands—3 deer; however, antlerless deer may be taken only Oct. 1–Jan. 31.	Aug. 1–Jan. 31.

TABLE 8 TO PARAGRAPH (n)(8)—Continued

Harvest limits	Open season
Elk: Kodiak, Ban, Uganik, and Afognak Islands—1 elk per household by Federal registration permit only. The season will be closed by announcement of the Refuge Manager, Kodiak National Wildlife Refuge, when the combined Federal/State harvest reaches 15% of the herd.	Sep. 15–Nov. 30.
Fox, Red (including Cross, Black and Silver Phases): 2 foxes	Sep. 1–Feb. 15.
Hare (Snowshoe): No limit	July 1–June 30.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver: 30 beaver per season	Nov. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Mar. 31.
Marten: No limit	Nov. 10–Jan. 31.
Mink and Weasel: No limit	Nov. 10–Jan. 31.
Muskrat: No limit	Nov. 10–June 10.
Otter: No limit	Nov. 10–Jan. 31.

(9) *Unit 9.* (i) Unit 9 consists of the Alaska Peninsula and adjacent islands, including drainages east of False Pass, Pacific Ocean drainages west of and excluding the Redoubt Creek drainage; drainages into the south side of Bristol Bay, drainages into the north side of Bristol Bay east of Etolin Point, and including the Sanak and Shumagin Islands:

(A) Unit 9A consists of that portion of Unit 9 draining into Shelikof Strait and Cook Inlet between the southern boundary of Unit 16 (Redoubt Creek) and the northern boundary of Katmai National Park and Preserve.

(B) Unit 9B consists of the Kvichak River drainage except those lands drained by the Kvichak River/Bay between the Alagnak River drainage and the Naknek River drainage.

(C) Unit 9C consists of the Alagnak (Branch) River drainage, the Naknek River drainage, lands drained by the Kvichak River/Bay between the Alagnak River drainage and the Naknek River drainage, and all land and water within Katmai National Park and Preserve.

(D) Unit 9D consists of all Alaska Peninsula drainages west of a line from the southernmost head of Port Moller to the head of American Bay, including the Shumagin Islands and other islands of Unit 9 west of the Shumagin Islands.

(E) Unit 9E consists of the remainder of Unit 9.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public lands:

(A) You may not take wildlife for subsistence uses in Katmai National Park; and

(B) You may not use motorized vehicles, except aircraft, boats, or snowmobiles used for hunting and transporting a hunter or harvested animal parts from Aug. 1 through Nov. 30 in the Naknek Controlled Use Area, which includes all of Unit 9C within the Naknek River drainage upstream from and including the King Salmon Creek drainage; however, you may use a motorized vehicle on the Naknek-King Salmon, Lake Camp, and Rapids Camp roads and on the King Salmon Creek trail, and on frozen surfaces of the Naknek River and Big Creek.

(iii) Unit-specific regulations:

(A) If you have a trapping license, you may use a firearm to take beaver in Unit 9B from April 1 through May 31 and in the remainder of Unit 9 from April 1 through 30.

(B) You may hunt brown bear by State registration permit in lieu of a resident tag in Unit 9B, except that portion within the Lake Clark National Park and Preserve, if you have obtained a State registration permit prior to hunting.

(C) In Unit 9B, Lake Clark National Park and Preserve, residents of Iliamna, Newhalen, Nondalton, Pedro Bay, Port Alsworth, and that portion of the park resident zone in Unit 9B and 13.440 permit holders may hunt brown bear by Federal registration permit in lieu of a resident tag. The season will be closed when 4 females or 10 bears have been taken, whichever occurs first. The permits will be issued and closure announcements made by the Superintendent Lake Clark National Park and Preserve.

(D) Residents of Iliamna, Newhalen, Nondalton, Pedro Bay, and Port Alsworth may take up to a total of 10 bull moose in Unit 9B for ceremonial purposes, under the terms of a Federal registration permit from July 1 through June 30. Permits will be issued to individuals only at the request of a local organization. This 10-moose limit is not cumulative with that permitted for potlatches by the State.

(E) For Units 9C and 9E only, a federally qualified subsistence user (recipient) of Units 9C and 9E may designate another federally qualified subsistence user of Units 9C and 9E to take bull caribou on his or her behalf. The designated hunter must obtain a designated hunter permit and must return a completed harvest report and turn over all meat to the recipient. There is no restriction on the number of possession limits the designated hunter may have in his/her possession at any one time.

(F) For Unit 9D, a federally qualified subsistence user (recipient) may designate another federally qualified subsistence user to take caribou on his or her behalf. The designated hunter must obtain a designated hunter permit and must return a completed harvest report. The designated hunter may hunt for any number of recipients but may have no more than four harvest limits in his/her possession at any one time.

(G) The communities of False Pass, King Cove, Cold Bay, Sand Point, and Nelson Lagoon annually may each take, from October 1 through December 31 or May 10 through 25, one brown bear for ceremonial purposes, under the terms of a Federal registration permit. A permit will be issued to an individual only at the request of a local organization. The brown bear may be taken from either Unit 9D or Unit 10 (Unimak Island) only.

(H) You may hunt brown bear in Unit 9E with a Federal registration permit in lieu of a State locking tag if you have obtained a Federal registration permit prior to hunting.

TABLE 9 TO PARAGRAPH (n)(9)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear:	
Unit 9B, Lake Clark National Park and Preserve—Rural residents of Iliamna, Newhalen, Nondalton, Pedro Bay, Port Alsworth, residents of that portion of the park resident zone in Unit 9B; and 13.440 permit holders—1 bear by Federal registration permit only.	July 1–June 30.
The season will be closed by the Lake Clark National Park and Preserve Superintendent when 4 females or 10 bear have been taken, whichever occurs first.	
Unit 9B, remainder—1 bear by State registration permit only	Sep. 1–May 31.
Unit 9C—1 bear by Federal registration permit only	Oct. 1–May 31.
The season will be closed by the Katmai National Park and Preserve Superintendent in consultation with BLM and FWS land managers and ADF&G, when 6 females or 10 bear have been taken, whichever occurs first.	
Unit 9E—1 bear by Federal registration permit	Sep. 25–Dec. 31. Apr. 15–May 25.
Caribou:	
Unit 9A—up to 2 caribou by State registration permit	Season may be announced between Aug. 1–Mar. 15.
Unit 9B—up to 2 caribou by State registration permit	Season may be announced between Aug. 1–Mar. 31.
Unit 9C, that portion within the Alagnak River drainage—up to 2 caribou by State registration permit	Season may be announced between Aug. 1–Mar. 15.
Unit 9C, that portion draining into the Naknek River from the north, and Graveyard Creek and Coffee Creek—up to 2 caribou by State registration permit.	Season may be announced between Aug. 1–Mar. 15.
Unit 9C, remainder—1 bull by Federal registration permit or State permit. Federal public lands are closed to the taking of caribou except by residents of Unit 9C and Egegik..	May be announced.
Unit 9D—1–4 caribou by Federal registration permit only	Aug. 1–Sep. 30. Nov. 15–Mar. 31.
Unit 9E—1 bull by Federal registration permit or State permit. Federal public lands are closed to the taking of caribou except by residents of Unit 9E, Nelson Lagoon, and Sand Point..	May be announced.
Sheep:	
Unit 9B, that portion within Lake Clark National Park and Preserve—1 ram with ¾ curl or larger horn by Federal registration permit only. By announcement of the Lake Clark National Park and Preserve Superintendent, the summer/fall season will be closed when up to 5 sheep are taken and the winter season will be closed when up to 2 sheep are taken..	July 15–Oct. 15. Jan. 1–Apr. 1.
Unit 9B, remainder—1 ram with ⅞ curl or larger horn by Federal registration permit only	Aug. 10–Oct. 10.
Unit 9, remainder—1 ram with ⅞ curl or larger horn	Aug. 10–Sep. 20.
Moose:	
Unit 9A—1 bull by State registration permit	Sep. 1–15.
Unit 9B—1 bull by State registration permit	Sep. 1–20. Dec. 1–Jan. 15.
Unit 9C, that portion draining into the Naknek River from the north—1 bull by State registration permit	Sep. 1–20. Dec. 1–31.
Unit 9C, that portion draining into the Naknek River from the south—1 bull by State registration permit. Public lands are closed during December for the hunting of moose, except by federally qualified subsistence users hunting under these regulations..	Aug. 20–Sep. 20. Dec. 1–31.
Unit 9C, remainder—1 bull by State registration permit	Sep. 1–20. Dec. 15–Jan. 15.
Unit 9D—1 bull by Federal registration permit. Federal public lands will be closed by announcement of the Izembek Refuge Manager to the harvest of moose when a total of 10 bulls have been harvested between State and Federal hunts..	Dec. 15–Jan. 20.
Unit 9E—1 bull by State registration permit; however, only antlered bulls may be taken Dec. 1–Jan. 31	Sep. 1–25. Dec. 1–Jan. 31.
Beaver: Unit 9B and 9E—2 beaver per day	Apr. 15–May 31.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Arctic (Blue and White): No limit	Dec. 1–Mar. 15.
Fox, Red (including Cross, Black and Silver Phases): 2 foxes	Sep. 1–Feb. 15.
Hare:	
Snowshoe hare: No limit	July 1–June 30.
Alaska hare: 1 per day, 4 per season	Nov. 1–Mar. 31.
Lynx: 2 lynx	Nov. 10–Feb. 28.
Wolf: 10 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce): 15 per day, 30 in possession	Aug. 10–Apr. 30.
Ptarmigan (Rock, Willow, and White-tailed): 10 per day, 20 in possession	Aug. 10–last day of Feb.
Trapping	
Beaver:	
No limit	Oct. 10–Mar. 31.
2 beaver per day; only firearms may be used	Apr. 15–May 31.
Coyote: No limit	Nov. 10–Mar. 31.

TABLE 9 TO PARAGRAPH (n)(9)—Continued

Harvest limits	Open season
Fox, Arctic (Blue and White): No limit	Nov. 10–Feb. 28.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Feb. 28.
Lynx: No limit	Nov. 10–Feb. 28.
Marten: No limit	Nov. 10–Feb. 28.
Mink and Weasel: No limit	Nov. 10–Feb. 28.
Muskrat: No limit	Nov. 10–June 10.
Otter: No limit	Nov. 10–Mar. 31.
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: No limit	Nov. 10–Feb. 28.

(10) *Unit 10.* (i) Unit 10 consists of the Aleutian Islands, Unimak Island, and the Pribilof Islands.

(ii) You may not take any wildlife species for subsistence uses on Otter Island in the Pribilof Islands.

(iii) In Unit 10—Unimak Island only, a federally qualified subsistence user (recipient) may designate another federally qualified subsistence user to take caribou on his or her behalf. The designated hunter must obtain a designated hunter permit and must return a completed harvest report. The designated hunter may hunt for any number of recipients but may have no more than four harvest limits in his/her possession at any one time.

(iv) The communities of False Pass, King Cove, Cold Bay, Sand Point, and Nelson Lagoon annually may each take, from October 1 through December 31 or May 10 through 25, one brown bear for ceremonial purposes, under the terms of a Federal registration permit. A permit will be issued to an individual only at the request of a local organization. The brown bear may be taken from either Unit 9D or Unit 10 (Unimak Island) only.

TABLE 10 TO PARAGRAPH (n)(10)

Harvest limits	Open season
Hunting	
Caribou:	
Unit 10, Unimak Island only—1 bull by Federal registration permit	Aug. 1–Sep. 30.
Unit 10, remainder—No limit	July 1–June 30.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Arctic (Blue and White Phase): No limit	July 1–June 30.
Fox, Red (including Cross, Black and Silver Phases): 2 foxes	Sep. 1–Feb. 15.
Wolf: 5 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Ptarmigan (Rock and Willow): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Arctic (Blue and White Phase): No limit	July 1–June 30.
Fox, Red (including Cross, Black and Silver Phases): 2 foxes	Sep. 1–Feb. 28.
Mink and Weasel: No limit	Nov. 10–Feb. 28.
Muskrat: No limit	Nov. 10–June 10.
Otter: No limit	Nov. 10–Mar. 31.
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: No limit	Nov. 10–Feb. 28.

(11) *Unit 11.* Unit 11 consists of that area draining into the headwaters of the Copper River south of Suslota Creek and the area drained by all tributaries into the east bank of the Copper River between the confluence of Suslota Creek with the Slana River and Miles Glacier.

(i) Unit-specific regulations:

(A) You may use bait to hunt black and brown bear between April 15 and June 15.

(B) One moose without calf may be taken from June 20 through July 31 in the Wrangell-St. Elias National Park and Preserve in Unit 11 or Unit 12 for the Batzulnetas Culture Camp. Two hunters from either Chistochina or Mentasta Village may be designated by the Mt. Sanford Tribal Consortium to receive the Federal subsistence harvest permit. The permit may be obtained from a Wrangell-St. Elias National Park and Preserve office.

(C) For federally qualified subsistence users living within the Ahtna traditional communities of Chistochina, Chitina, Copper Center, Gakona, Gulkana, Mentasta Lake, and Tazlina, a community harvest system for moose is authorized on Federal public lands within Unit 11, subject to the framework established by the Federal Subsistence Board.

(*1*) The boundaries of the communities are the most recent Census Designated Places as defined by the U.S. Census Bureau.

(*2*) Participants in the community harvest system may not designate another individual to harvest on their behalf any species for which they register within the community harvest system but may serve as a designated hunter, pursuant to 50 CFR 100.25(e).

(*3*) Community harvest limit for the species authorized in the community harvest system is the sum of individual harvest limits of the participants in the system.

(*4*) Harvest reporting will take the form of reports collected from hunters by the Ahtna Intertribal Resource Commission and submitted directly to land managers and the Office of Subsistence Management, rather than through Federal registration permits, joint State/Federal registration permits, or State harvest tickets.

(ii) A joint permit may be issued to a pair of a minor and an elder to hunt sheep during the Aug. 1–Oct. 20 hunt. The following conditions apply:

(A) The permittees must be a minor aged 8 to 15 years old and an accompanying adult 60 years of age or older.

(B) Both the elder and the minor must be federally qualified subsistence users with a positive customary and traditional use determination for the area they want to hunt.

(C) The minor must hunt under the direct immediate supervision of the accompanying adult, who is responsible for ensuring that all legal requirements are met.

(D) Only one animal may be harvested with this permit. The sheep harvested will count against the harvest limits of both the minor and accompanying adult.

TABLE 11 TO PARAGRAPH (n)(11)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear: 1 bear	Aug. 10–June 15.
Caribou: 1 bull by Federal registration permit	May be announced.
Sheep:	
1 ram	Aug. 10–Sep. 20.
1 sheep by Federal registration permit only by persons 60 years of age or older. Ewes accompanied by lambs or lambs may not be taken.	Aug. 1–Oct. 20.
Goat:	
Unit 11, that portion within the Wrangell-St. Elias National Park and Preserve that is bounded by the Chitina and Nizina rivers on the south, the Kennicott River and glacier on the southeast, and the Root Glacier on the east—1 goat by Federal registration permit only.	Aug. 25–Dec. 31.
Unit 11, the remainder of the Wrangell-St. Elias National Park and Preserve—1 goat by Federal registration permit only.	Aug. 10–Dec. 31.
Unit 11, that portion outside of the Wrangell-St. Elias National Park and Preserve	No open season.
Federal public lands will be closed by announcement of the Superintendent, Wrangell-St. Elias National Park and Preserve, to the harvest of goats when a total of 45 goats has been harvested between Federal and State hunts.	
Moose:	
Unit 11, that portion draining into the east bank of the Copper River upstream from and including the Slana River drainage—1 antlered bull by joint Federal/State registration permit.	Aug. 20–Sep. 20.
Unit 11, that portion south and east of a line running along the north bank of the Chitina River, the north and west banks of the Nazina River, and the west bank of West Fork of the Nazina River, continuing along the western edge of the West Fork Glacier to the summit of Regal Mountain—1 bull by Federal registration permit. However, during the period Aug. 20–Sep. 20, only an antlered bull may be taken.	Aug. 20–Sep. 20. Nov. 20–Jan. 20.
Unit 11, remainder—1 antlered bull by Federal registration permit only	Aug. 20–Sep. 20.
Muskrat: No limit	Sep. 20–June 10.
Beaver: 1 beaver per day, 1 in possession	June 1–Oct. 10.
Coyote: 10 coyotes	Aug. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 10–Feb. 28.
Wolf: 10 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Feb. 28.
Grouse (Spruce, Ruffed, and Sharp-tailed): 15 per day, 30 in possession	Aug. 10–Mar. 31.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Mar. 31.
Trapping	
Beaver: No limit	Sep. 25–May 31.
Coyote: No limit	Nov. 10–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Feb. 28.
Lynx: No limit	Nov. 10–Feb. 28.
Marten: No limit	Nov. 10–Feb. 28.
Mink and Weasel: No limit	Nov. 10–Feb. 28.
Muskrat: No limit	Nov. 10–June 10.
Otter: No limit	Nov. 10–Mar. 31.
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: No limit	Nov. 10–Feb. 28.

(12) *Unit 12.* Unit 12 consists of the Tanana River drainage upstream from the Robertson River, including all drainages into the east bank of the Robertson River, and the White River drainage in Alaska, but excluding the Ladue River drainage.

(i) Unit-specific regulations:

(A) You may use bait to hunt black and brown bear between April 15 and June 30; you may use bait to hunt wolves on FWS and BLM lands.

(B) You may not use a steel trap, or a snare using cable smaller than 3/32-inch diameter to trap coyotes or wolves in Unit 12 during April and October.

(C) One moose without calf may be taken from June 20 through July 31 in the Wrangell-St. Elias National Park and Preserve in Unit 11 or 12 for the Batzulnetas Culture Camp. Two hunters from either Chistochina or Mentasta Village may be designated by the Mt. Sanford Tribal Consortium to receive the Federal subsistence harvest permit. The permit may be obtained from a Wrangell-St. Elias National Park and Preserve office.

(D) A community harvest system for caribou and moose is authorized on Federal public lands in Unit 12 within the Tok and Little Tok River drainages south of the Tok River bridge and east of the Tok Cutoff Road, and within the Nabesna River drainage west of the east bank of the Nabesna River upstream from the southern boundary of Tetlin National Wildlife Refuge and that portion of Unit 12 that is east of the Nabesna River and south of the Pickerel Lake Winter Trail running southeast from Pickerel Lake to the Canadian border. This community harvest system is for federally qualified subsistence users living within the Ahtna traditional communities of Chistochina, Chitina, Copper Center, Gakona, Gulkana, Mentasta Lake, and Tazlina and is subject to the framework established by the Federal Subsistence Board.

(*1*) The boundaries of the communities are the most recent Census Designated Places as defined by the U.S. Census Bureau.

(*2*) Participants in the community harvest system may not designate another individual to harvest on their behalf any species for which they register within the community harvest system but may serve as a designated hunter, pursuant to 50 CFR 100.25(e).

(*3*) The community harvest limit for the species authorized in the community harvest system is the sum of individual harvest limits of the participants in the system.

(*4*) Harvest reporting will take the form of reports collected from hunters by the Ahtna Intertribal Resource Commission and submitted directly to the land managers and the Office of Subsistence Management, rather than through Federal registration permits, joint State/Federal registration permits, or State harvest tickets.

(*5*) Participants must abide by customary and traditional use determinations.

(ii) A joint permit may be issued to a pair of a minor and an elder to hunt sheep during the Aug. 1–Oct. 20 hunt. The following conditions apply:

(A) The permittees must be a minor aged 8 to 15 years old and an accompanying adult 60 years of age or older.

(B) Both the elder and the minor must be federally qualified subsistence users with a positive customary and traditional use determination for the area they want to hunt.

(C) The minor must hunt under the direct immediate supervision of the accompanying adult, who is responsible for ensuring that all legal requirements are met.

(D) Only one animal may be harvested with this permit. The sheep harvested will count against the harvest limits of both the minor and accompanying adult.

TABLE 12 TO PARAGRAPH (n)(12)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear: 1 bear	Aug. 10–June 30.
Caribou:	
Unit 12, that portion within the Wrangell-St. Elias National Park that lies west of the Nabesna River and the Nabesna Glacier. All hunting of caribou is prohibited on Federal public lands..	No open season.
Unit 12, that portion east of the Nabesna River and the Nabesna Glacier and south of the Winter Trail running southeast from Pickerel Lake to the Canadian border—1 bull by Federal registration permit only.	Aug. 10–Sep. 30.
Federal public lands are closed to the harvest of caribou except by federally qualified subsistence users hunting under these regulations.	
Unit 12, remainder—1 bull	Sep. 1–20.
Unit 12, remainder—1 caribou may be taken by a Federal registration permit during a winter season to be announced. Dates for a winter season to occur between Oct. 1 and Apr. 30, and sex of the animals to be taken will be announced by the Tetlin National Wildlife Refuge Manager in consultation with the Wrangell-St. Elias National Park and Preserve Superintendent, Alaska Department of Fish and Game area biologists, and Chairs of the Eastern Interior Regional Advisory Council and Upper Tanana/Fortymile Fish and Game Advisory Committee.	Winter season to be announced.
Sheep:	
Unit 12—1 ram with full curl or larger horn	Aug. 10–Sep. 20.
Unit 12, that portion within Wrangell-St. Elias National Park and Preserve—1 ram with full curl horn or larger by Federal registration permit only by persons 60 years of age or older.	Aug. 1–Oct. 20.
Moose:	
Unit 12, that portion within the Tetlin National Wildlife Refuge and those lands within the Wrangell-St. Elias National Preserve north and east of a line formed by the Pickerel Lake Winter Trail from the Canadian border to Pickerel Lake—1 antlered bull by Federal registration permit.	Aug. 24–Sep. 20. Nov. 1–Feb. 28.
Unit 12, that portion east of the Nabesna River and Nabesna Glacier, and south of the Winter Trail running southeast from Pickerel Lake to the Canadian border—1 antlered bull.	Aug. 24–Sep. 30.
Unit 12, that portion within the Nabesna River drainage west of the east bank of the Nabesna River upstream from the southern boundary of Tetlin National Wildlife Refuge—1 antlered bull by joint Federal/State registration permit only.	Aug. 20–Sep. 20.
Unit 12, remainder—1 bull	Aug. 24–28. Sep. 8–20.
Beaver: Unit 12, Wrangell-St. Elias National Park and Preserve—6 beaver per season. Meat from harvested beaver must be salvaged for human consumption.	Sep. 20–May 15.
Coyote: 10 coyotes	Aug. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.

TABLE 12 TO PARAGRAPH (n)(12)—Continued

Harvest limits	Open season
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 1–Mar. 15.
Wolf: 10 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31
Grouse (Spruce, Ruffed, and Sharp-tailed): 15 per day, 30 in possession	Aug. 10–Mar. 31.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver: No limit. Hide or meat must be salvaged. Traps, snares, bow and arrow, or firearms may be used	Sep. 15–Jun 10.
Coyote: No limit	Oct. 15–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 1–Feb. 28.
Lynx: No limit	Nov. 1–Mar. 15.
Marten: No limit	Nov. 1–Feb. 28.
Mink and Weasel: No limit	Nov. 1–Feb. 28.
Muskrat: No limit	Sep. 20–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Oct. 1–Apr. 30.
Wolverine: No limit	Nov. 1–Feb. 28.

(13) *Unit 13.* (i) Unit 13 consists of that area westerly of the east bank of the Copper River and drained by all tributaries into the west bank of the Copper River from Miles Glacier and including the Slana River drainages north of Suslota Creek; the drainages into the Delta River upstream from Falls Creek and Black Rapids Glacier; the drainages into the Nenana River upstream from the southeastern corner of Denali National Park at Windy; the drainage into the Susitna River upstream from its junction with the Chulitna River; the drainage into the east bank of the Chulitna River upstream to its confluence with Tokositna River; the drainages of the Chulitna River (south of Denali National Park) upstream from its confluence with the Tokositna River; the drainages into the north bank of the Tokositna River upstream to the base of the Tokositna Glacier; the drainages into the Tokositna Glacier; the drainages into the east bank of the Susitna River between its confluences with the Talkeetna and Chulitna Rivers; the drainages into the north and east bank of the Talkeetna River including the Talkeetna River to its confluence with Clear Creek, the eastside drainages of a line going up the south bank of Clear Creek to the first unnamed creek on the south, then up that creek to lake 4408, along the northeastern shore of lake 4408, then southeast in a straight line to the northernmost fork of the Chickaloon River; the drainages into the east bank of the Chickaloon River below the line from lake 4408; the drainages of the Matanuska River above its confluence with the Chickaloon River:

(A) Unit 13A consists of that portion of Unit 13 bounded by a line beginning at the Chickaloon River bridge at Mile 77.7 on the Glenn Highway, then along the Glenn Highway to its junction with the Richardson Highway, then south along the Richardson Highway to the foot of Simpson Hill at Mile 111.5, then east to the east bank of the Copper River, then northerly along the east bank of the Copper River to its junction with the Gulkana River, then northerly along the west bank of the Gulkana River to its junction with the West Fork of the Gulkana River, then westerly along the west bank of the West Fork of the Gulkana River to its source, an unnamed lake, then across the divide into the Tyone River drainage, down an unnamed stream into the Tyone River, then down the Tyone River to the Susitna River, then down the south bank of the Susitna River to the mouth of Kosina Creek, then up Kosina Creek to its headwaters, then across the divide and down Aspen Creek to the Talkeetna River, then southerly along the boundary of Unit 13 to the Chickaloon River bridge, the point of beginning.

(B) Unit 13B consists of that portion of Unit 13 bounded by a line beginning at the confluence of the Copper River and the Gulkana River, then up the east bank of the Copper River to the Gakona River, then up the Gakona River and Gakona Glacier to the boundary of Unit 13, then westerly along the boundary of Unit 13 to the Susitna Glacier, then southerly along the west bank of the Susitna Glacier and the Susitna River to the Tyone River, then up the Tyone River and across the divide to the headwaters of the West Fork of the Gulkana River, then down the West Fork of the Gulkana River to the confluence of the Gulkana River and the Copper River, the point of beginning.

(C) Unit 13C consists of that portion of Unit 13 east of the Gakona River and Gakona Glacier.

(D) Unit 13D consists of that portion of Unit 13 south of Unit 13A.

(E) Unit 13E consists of the remainder of Unit 13.

(ii) Within the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public lands:

(A) You may not take wildlife for subsistence uses on lands within Mount McKinley National Park as it existed prior to December 2, 1980. Subsistence uses as authorized by this paragraph (n)(13) are permitted in Denali National Preserve and lands added to Denali National Park on December 2, 1980.

(B) You may not use motorized vehicles or pack animals for hunting Aug. 5–25 in the Delta Controlled Use Area, the boundary of which is defined as: a line beginning at the confluence of Miller Creek and the Delta River, then west to vertical angle benchmark Miller, then west to include all drainages of Augustana Creek and Black Rapids Glacier, then north and east to include all drainages of McGinnis Creek to its confluence with the Delta River, then east in a straight line across the Delta River to Mile 236.7 Richardson Highway, then north along the Richardson Highway to its junction with the Alaska Highway, then east along the Alaska Highway to the west bank of the Johnson River, then south along the west bank of the Johnson River and Johnson Glacier to the head of the Cantwell Glacier, then west along the north bank of the Cantwell Glacier and Miller Creek to the Delta River.

(C) Except for access and transportation of harvested wildlife on Sourdough and Haggard Creeks, Middle

Fork trails, or other trails designated by the Board, you may not use motorized vehicles for subsistence hunting in the Sourdough Controlled Use Area. The Sourdough Controlled Use Area consists of that portion of Unit 13B bounded by a line beginning at the confluence of Sourdough Creek and the Gulkana River, then northerly along Sourdough Creek to the Richardson Highway at approximately Mile 148, then northerly along the Richardson Highway to the Middle Fork Trail at approximately Mile 170, then westerly along the trail to the Gulkana River, then southerly along the east bank of the Gulkana River to its confluence with Sourdough Creek, the point of beginning.

(D) You may not use any motorized vehicle or pack animal for hunting, including the transportation of hunters, their hunting gear, and/or parts of game from July 26 through September 30 in the Tonsina Controlled Use Area. The Tonsina Controlled Use Area consists of that portion of Unit 13D bounded on the west by the Richardson Highway from the Tiekel River to the Tonsina River at Tonsina, on the north along the south bank of the Tonsina River to where the Edgerton Highway crosses the Tonsina River, then along the Edgerton Highway to Chitina, on the east by the Copper River from Chitina to the Tiekel River, and on the south by the north bank of the Tiekel River.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15.

(B) Upon written request by the Camp Director to the Glennallen Field Office, 2 caribou, sex to be determined by the Glennallen Field Office Manager of the BLM, may be taken from Aug. 10 through Sep. 30 or Oct. 21 through Mar. 31 by Federal registration permit for the Hudson Lake Residential Treatment Camp. Additionally, 1 bull moose may be taken Aug. 1 through Sep. 20. The animals may be taken by any federally qualified hunter designated by the Camp Director. The hunter must have in his/her possession the permit and a designated hunter permit during all periods that are being hunted.

(C) A community harvest system for caribou and moose is authorized on Federal public lands within Unit 13, subject to the framework established by the Federal Subsistence Board, for federally qualified subsistence users living within the Ahtna traditional communities of Cantwell, Chistochina, Chitina, Copper Center, Gakona, Gulkana, Mentasta Lake, and Tazlina.

(*1*) The boundaries of the communities are the most recent Census Designated Places as defined by the U.S. Census Bureau.

(*2*) Participants in the community harvest system may not designate another individual to harvest on their behalf any species for which they register within the community harvest system but may serve as a designated hunter, pursuant to 50 CFR 100.25(e).

(*3*) The community harvest limit for the species authorized in the community harvest system is the sum of individual harvest limits of the participants in the system.

(*4*) Harvest reporting will take the form of reports collected from hunters by the Ahtna Intertribal Resource Commission and submitted directly to the land managers and the Office of Subsistence Management, rather than through Federal registration permits, joint State/Federal registration permits, or State harvest tickets.

TABLE 13 TO PARAGRAPH (n)(13)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear: 1 bear. Bears taken within Denali National Park must be sealed within 5 days of harvest. That portion within Denali National Park will be closed by announcement of the Superintendent after 4 bears have been harvested.	Aug. 10–May 31.
Caribou:	
Units 13A and 13B—2 caribou by Federal registration permit only. The sex of animals that may be taken will be announced by the Glennallen Field Office Manager of the Bureau of Land Management in consultation with the Alaska Department of Fish and Game area biologist and Chairs of the Eastern Interior Regional Advisory Council and the Southcentral Regional Advisory Council.	Aug. 1–Sep. 30. Oct. 21–Mar. 31.
Unit 13, remainder—2 bulls by Federal registration permit only	Aug. 1–Sep. 30. Oct. 21–Mar. 31.
Sheep: Unit 13, excluding Unit 13D and the Tok Management Area and Delta Controlled Use Area—1 ram with 7/8 curl or larger horn.	Aug. 10–Sep. 20.
Moose:	
Unit 13E—1 antlered bull moose by Federal registration permit only; only 1 permit will be issued per household.	Aug. 1–Sep. 20.
Unit 13, remainder—1 antlered bull moose by Federal registration permit only	Aug. 1–Sep. 20.
Beaver: 1 beaver per day, 1 in possession	June 15–Sep. 10.
Coyote: 10 coyotes	Aug. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 10–Feb. 28.
Wolf: 10 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Feb. 28.
Grouse (Spruce, Ruffed, and Sharp-tailed): 15 per day, 30 in possession	Aug. 10–Mar. 31.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Mar. 31.
Trapping	
Beaver: No limit	Sep. 25–May 31.
Coyote: No limit	Nov. 10–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Feb. 28.
Lynx: No limit	Nov. 10–Feb. 28.
Marten: Unit 13—No limit	Nov. 10–Feb. 28.
Mink and Weasel: No limit	Nov. 10–Feb. 28.

TABLE 13 TO PARAGRAPH (n)(13)—Continued

Harvest limits	Open season
Muskrat: No limit	Sep. 25–June 10.
Otter: No limit	Nov. 10–Mar. 31.
Wolf: No limit	Oct. 15–Apr. 30.
Wolverine: No limit	Nov. 10–Feb. 28.

(14) *Unit 14.* (i) Unit 14 consists of drainages into the northern side of Turnagain Arm west of and excluding the Portage Creek drainage, drainages into Knik Arm excluding drainages of the Chickaloon and Matanuska Rivers in Unit 13, drainages into the northern side of Cook Inlet east of the Susitna River, drainages into the east bank of the Susitna River downstream from the Talkeetna River, and drainages into the south and west bank of the Talkeetna River to its confluence with Clear Creek, the western side drainages of a line going up the south bank of Clear Creek to the first unnamed creek on the south, then up that creek to lake 4408, along the northeastern shore of lake 4408, then southeast in a straight line to the northernmost fork of the Chickaloon River:

(A) Unit 14A consists of drainages in Unit 14 bounded on the west by the east bank of the Susitna River, on the north by the north bank of Willow Creek and Peters Creek to its headwaters, then east along the hydrologic divide separating the Susitna River and Knik Arm drainages to the outlet creek at lake 4408, on the east by the eastern boundary of Unit 14, and on the south by Cook Inlet, Knik Arm, the south bank of the Knik River from its mouth to its junction with Knik Glacier, across the face of Knik Glacier and along the northern side of Knik Glacier to the Unit 6 boundary;

(B) Unit 14B consists of that portion of Unit 14 north of Unit 14A; and

(C) Unit 14C consists of that portion of Unit 14 south of Unit 14A.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public lands:

(A) You may not take wildlife for subsistence uses in the Fort Richardson and Elmendorf Air Force Base Management Areas, consisting of the Fort Richardson and Elmendorf Military Reservations; and

(B) You may not take wildlife for subsistence uses in the Anchorage Management Area, consisting of all drainages south of Elmendorf and Fort Richardson military reservations and north of and including Rainbow Creek.

(iii) Unit-specific regulations:

TABLE 14 TO PARAGRAPH (n)(14)

Harvest limits	Open season
Hunting	
Black Bear: Unit 14C—1 bear	July 1–June 30.
Beaver: Unit 14C—1 beaver per day, 1 in possession	May 15–Oct. 31.
Coyote: Unit 14C—2 coyotes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): Unit 14C—2 foxes	Nov. 1–Feb. 15.
Hare (Snowshoe): Unit 14C—5 hares per day	Sep. 8–Apr. 30.
Lynx: Unit 14C—2 lynx	Dec. 1–Jan. 31.
Wolf: Unit 14C—5 wolves	Aug. 10–Apr. 30.
Wolverine: Unit 14C—1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce and Ruffed): Unit 14C—5 per day, 10 in possession	Sep. 8–Mar. 31.
Ptarmigan (Rock, Willow, and White-tailed): Unit 14C—10 per day, 20 in possession	Sep. 8–Mar. 31.
Trapping	
Beaver: Unit 14C, that portion within the drainages of Glacier Creek, Kern Creek, Peterson Creek, the Twentymile River and the drainages of Knik River outside Chugach State Park—20 beaver per season.	Dec. 1–Apr. 15.
Coyote: Unit 14C—No limit	Nov. 10–Feb. 28.
Fox, Red (including Cross, Black and Silver Phases): Unit 14C—1 fox	Nov. 10–Feb. 28.
Lynx: Unit 14C—No limit	Dec. 15–Jan. 31.
Marten: Unit 14C—No limit	Nov. 10–Jan. 31.
Mink and Weasel: Unit 14C—No limit	Nov. 10–Jan. 31.
Muskrat: Unit 14C—No limit	Nov. 10–May 15.
Otter: Unit 14C—No limit	Nov. 10–Feb. 28.
Wolf: Unit 14C—No limit	Nov. 10–Feb. 28.
Wolverine: Unit 14C—2 wolverines	Nov. 10–Jan. 31.

(15) *Unit 15.* (i) Unit 15 consists of that portion of the Kenai Peninsula and adjacent islands draining into the Gulf of Alaska, Cook Inlet, and Turnagain Arm from Gore Point to the point where longitude line 150°00′ W crosses the coastline of Chickaloon Bay in Turnagain Arm, including that area lying west of longitude line 150°00′ W to the mouth of the Russian River, then southerly along the Chugach National Forest boundary to the upper end of Upper Russian Lake; and including the drainages into Upper Russian Lake west of the Chugach National Forest boundary:

(A) Unit 15A consists of that portion of Unit 15 north of the north bank of the Kenai River and the northern shore of Skilak Lake;

(B) Unit 15B consists of that portion of Unit 15 south of the north bank of the Kenai River and the northern shore of Skilak Lake, and north of the north bank

of the Kasilof River, the northern shore of Tustumena Lake, Glacier Creek, and Tustumena Glacier; and

(C) Unit 15C consists of the remainder of Unit 15.

(ii) You may not take wildlife, except for grouse, ptarmigan, and hares that may be taken only from October 1 through March 1 by bow and arrow only, in the Skilak Loop Management Area, which consists of that portion of Unit 15A bounded by a line beginning at the easternmost junction of the Sterling Highway and the Skilak Loop (milepost 76.3), then due south to the south bank of the Kenai River, then southerly along the south bank of the Kenai River to its confluence with Skilak Lake, then westerly along the northern shore of Skilak Lake to Lower Skilak Lake Campground, then northerly along the Lower Skilak Lake Campground Road and the Skilak Loop Road to its westernmost junction with the Sterling Highway, then easterly along the Sterling Highway to the point of beginning.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15;

(B) You may not trap furbearers for subsistence in the Skilak Loop Wildlife Management Area;

(C) You may not trap marten in that portion of Unit 15B east of the Kenai River, Skilak Lake, Skilak River, and Skilak Glacier; and

(D) You may not take red fox in Unit 15 by any means other than a steel trap or snare.

TABLE 15 TO PARAGRAPH (n)(15)

Harvest limits	Open season
Hunting	
Black Bear:	
Units 15A and 15B—2 bears by Federal registration permit	July 1–June 30.
Unit 15C—3 bears	July 1–June 30.
Brown Bear: Unit 15—1 bear every 4 regulatory years by Federal registration permit. The season may be opened or closed by announcement from the Kenai National Wildlife Refuge Manager after consultation with ADF&G and the Chair of the Southcentral Alaska Subsistence Regional Advisory Council.	Sep. 1–Nov. 30, to be announced and Apr. 1–June 15, to be announced.
Caribou:	
Unit 15B, within the Kenai National Wildlife Refuge Wilderness Area—1 caribou by Federal drawing permit	Aug. 10–Sep. 20.
Unit 15C, north of the Fox River and east of Windy Lake—1 caribou by Federal drawing permit	Aug. 10–Sep. 20.
Unit 15, remainder	No open season.
Goat: 1 goat by Federal drawing permit. Kids or nannies accompanied by kids may not be taken	Aug. 10–Nov. 14.
Moose:	
Unit 15A—Skilak Loop Wildlife Management Area	No open season.
Units 15A remainder, 15B, and 15C—1 antlered bull with spike-fork or 50-inch antlers or with 3 or more brow tines on either antler, by Federal registration permit only.	Aug. 20–Sep. 25.
Units 15B and 15C—1 antlered bull with spike-fork or 50-inch antlers or with 3 or more brow tines on either antler, by Federal registration permit only. The Kenai NWR Refuge Manager is authorized to close the October–November season based on conservation concerns, in consultation with ADF&G and the Chair of the Southcentral Alaska Subsistence Regional Advisory Council.	Oct. 20–Nov. 10.
Unit 15C—1 cow by Federal registration permit only	Aug. 20–Sep. 25.
Sheep: 1 ram with ¾ curl horn or larger by Federal drawing permit	Aug 10–Sep. 20.
Coyote: No limit	Sep. 1–Apr. 30.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 10–Jan. 31.
Wolf:	
Unit 15, that portion within the Kenai National Wildlife Refuge—2 wolves	Aug. 10–Apr. 30.
Unit 15, remainder—5 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce): 15 per day, 30 in possession	Aug. 10–Mar. 31.
Grouse (Ruffed)	No open season.
Ptarmigan (Rock, Willow, and White-tailed):	
Unit 15A and 15B—20 per day, 40 in possession	Aug. 10–Mar. 31.
Unit 15C—20 per day, 40 in possession	Aug. 10–Dec. 31.
Unit 15C—5 per day, 10 in possession	Jan. 1–Mar. 31.
Trapping	
Beaver: 20 beaver per season	Nov. 10–Mar. 31.
Coyote: No limit	Nov. 10–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): 1 Fox	Nov. 10–Feb. 28.
Lynx: No limit	Jan. 1–31.
Marten:	
Unit 15B, that portion east of the Kenai River, Skilak Lake, Skilak River, and Skilak Glacier	No open season.
Remainder of Unit 15—No limit	Nov. 10–Jan. 31.
Mink and Weasel: No limit	Nov. 10–Jan. 31.
Muskrat: No limit	Nov. 10–May 15.
Otter: Unit 15—No limit	Nov. 10–Feb. 28.
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: Unit 15B and C—No limit	Nov. 10–Feb. 28.

(16) *Unit 16.* (i) Unit 16 consists of the drainages into Cook Inlet between Redoubt Creek and the Susitna River, including Redoubt Creek drainage, Kalgin Island, and the drainages on the western side of the Susitna River (including the Susitna River) upstream to its confluence with the Chulitna River; the drainages into the western side of the Chulitna River (including the Chulitna River) upstream to the Tokositna River, and drainages into the southern side of the Tokositna River upstream to the base of the Tokositna Glacier, including the drainage of the Kahiltna Glacier:

(A) Unit 16A consists of that portion of Unit 16 east of the east bank of the Yentna River from its mouth upstream to the Kahiltna River, east of the east bank of the Kahiltna River, and east of the Kahiltna Glacier; and

(B) Unit 16B consists of the remainder of Unit 16.

(ii) You may not take wildlife for subsistence uses in the Mount McKinley National Park, as it existed prior to December 2, 1980. Subsistence uses as authorized by this paragraph (n)(16) are permitted in Denali National Preserve and lands added to Denali National Park on December 2, 1980.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15.

(B) [Reserved]

TABLE 16 TO PARAGRAPH (n)(16)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Caribou: 1 caribou	Aug. 10–Oct. 31.
Moose:	
Unit 16B, Redoubt Bay Drainages south and west of, and including the Kustatan River drainage—1 bull	Sep. 1–15.
Unit 16B, Denali National Preserve only—1 bull by Federal registration permit. One Federal registration permit for moose issued per household.	Sep. 1–30. Dec. 1–Feb. 28.
Unit 16B, remainder—1 bull	Sep. 1–30. Dec. 1–Feb. 28.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 2 foxes	Sep. 1–Feb. 15.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Dec. 1–Jan. 31.
Wolf: 5 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce and Ruffed): 15 per day, 30 in possession	Aug. 10–Mar. 31.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Mar. 31.
Trapping	
Beaver: No limit	Oct. 10–May 15.
Coyote: No limit	Nov. 10–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Feb. 28.
Lynx: No limit	Dec. 15–Jan. 31.
Marten: No limit	Nov. 10–Feb. 28.
Mink and Weasel: No limit	Nov. 10–Jan. 31.
Muskrat: No limit	Nov. 10–June 10.
Otter: No limit	Nov. 10–Mar. 31.
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: No limit	Nov. 10–Feb. 28.

(17) *Unit 17.* (i) Unit 17 consists of drainages into Bristol Bay and the Bering Sea between Etolin Point and Cape Newenham, and all islands between these points including Hagemeister Island and the Walrus Islands:

(A) Unit 17A consists of the drainages between Cape Newenham and Cape Constantine, and Hagemeister Island and the Walrus Islands;

(B) Unit 17B consists of the Nushagak River drainage upstream from, and including the Mulchatna River drainage and the Wood River drainage upstream from the outlet of Lake Beverley; and

(C) Unit 17C consists of the remainder of Unit 17.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public lands:

(A) Except for aircraft and boats and in legal hunting camps, you may not use any motorized vehicle for hunting ungulates, bear, wolves, and wolverine, including transportation of hunters and parts of ungulates, bear, wolves, or wolverine in the Upper Mulchatna Controlled Use Area consisting of Unit 17B, from Aug. 1 through Nov. 1.

(B) [Reserved]

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 15.

(B) You may hunt brown bear by State registration permit in lieu of a resident tag if you have obtained a State registration permit prior to hunting.

(C) If you have a trapping license, you may use a firearm to take beaver in Unit 17 from April 15 through May 31. You may not take beaver with a firearm under a trapping license on National Park Service lands.

(D) In Unit 17, a snowmachine may be used to assist in the taking of a caribou, and caribou may be shot from a stationary snowmachine. ''Assist in the taking of a caribou'' means a snowmachine may be used to approach within 300 yards of a caribou at speeds under 15 miles per hour, in a manner that does not involve repeated approaches or that causes a caribou to run. A snowmachine may not be used to contact an animal or to pursue a fleeing caribou.

TABLE 17 TO PARAGRAPH (n)(17)

Harvest limits	Open season
Hunting	
Black Bear: 2 bears	Aug. 1–May 31.
Brown Bear: Unit 17—1 bear by State registration permit only	Sep. 1–May 31.
Caribou: Unit 17A, all drainages west of Right Hand Point—up to 2 caribou by State registration permit	Season may be announced between Aug. 1–Mar. 31.
Units 17A and 17C, that portion of 17A and 17C consisting of the Nushagak Peninsula south of the Igushik River, Tuklung River and Tuklung Hills, west to Tvativak Bay—up to 5 caribou by Federal registration permit.	Aug. 1–Mar. 31.
Public lands are closed to the taking of caribou except by federally qualified users unless the population estimate exceeds 900 caribou.	
Units 17A, remainder and 17C, remainder—selected drainages; a harvest limit of up to 2 caribou by State registration permit will be determined at the time the season is announced.	Season may be announced between Aug. 1 and Mar. 31.
Units 17B and 17C, that portion of 17C east of the Wood River and Wood River Lakes—up to 2 caribou by State registration permit.	Season may be announced between Aug. 1–Mar. 31.
Sheep: 1 ram with full curl or larger horn	Aug. 10–Sep. 20.
Moose: Unit 17A—1 bull by State registration permit; or	Aug. 25–Sep. 25.
1 antlerless moose by State registration permit; or	Aug. 25–Sep. 25.
Unit 17A—up to 2 moose; one antlered bull by State registration permit, one antlerless moose by State registration permit.	Up to a 31-day season may be announced between Dec. 1 and the last day of Feb.
Units 17B and 17C—one bull	Aug. 20–Sep. 15. Dec. 1–31.
During the period Aug. 20–Sep. 15—one bull by State registration permit; or	
During the period Sep. 1–15—one bull with spike-fork or 50-inch antlers or antlers with three or more brow tines on at least one side with a State harvest ticket; or	
During the period Dec. 1–31—one antlered bull by State registration permit.	
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Arctic (Blue and White Phase): No limit	Dec. 1–Mar. 15.
Fox, Red (including Cross, Black and Silver Phases): 2 foxes	Sep. 1–Feb. 15.
Hare:	
Snowshoe hare: No limit	July 1–June 30.
Alaska hare: 1 per day, 4 per season	Nov. 1–Mar. 31.
Lynx: 2 lynx	Nov. 10–Feb. 28.
Wolf: 10 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce and Ruffed): 15 per day, 30 in possession	Aug. 10–Apr. 30.
Ptarmigan (Rock and Willow): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver: Unit 17—No limit	Oct. 10–Mar. 31.
Unit 17—2 beaver per day. Only firearms may be used	Apr. 15–May 31.
Coyote: No limit	Nov. 10–Mar. 31.
Fox, Arctic (Blue and White Phase): No limit	Nov. 10–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Mar. 31.
Lynx: No limit	Nov. 10–Mar. 31.
Marten: No limit	Nov. 10–Feb. 28.
Mink and Weasel: No limit	Nov. 10–Feb. 28.
Muskrat: 2 muskrats	Nov. 10–Feb. 28.
Otter: No limit	Nov. 10–Mar. 31.
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: No limit	Nov. 10–Feb. 28.

(18) *Unit 18.* (i) Unit 18 consists of that area draining into the Yukon and Kuskokwim Rivers westerly and downstream from a line starting at the downriver boundary of Paimiut on the north bank of the Yukon River then south across the Yukon River to the northern terminus of the Paimiut Portage, then south along the Paimiut Portage to its intersection with Arhymot Lake, then south along the northern and western bank of Arhymot Lake to the outlet at Crooked Creek (locally known as Johnson River), then along the south bank of Crooked Creek downstream to the northern terminus of Crooked Creek to the Yukon-Kuskokwim Portage (locally known as the Mud Creek Tramway), then along the west side of the tramway to Mud Creek, then along the westerly bank of Mud Creek downstream to an unnamed slough of the Kuskokwim River (locally known as First Slough or Kalskag Slough), then along the west bank of this unnamed slough downstream to its confluence with the Kuskokwim River, then southeast across the Kuskokwim River to its southerly bank, then along the south bank of the Kuskokwim River upriver to the confluence of a Kuskokwim River slough locally known as Old River, then across Old River to the downriver terminus of the island formed by Old River and the Kuskokwim River, then along the north bank of the main channel of Old River to Igyalleq Creek (Whitefish Creek), then along the south and west bank of

Igyalleq Creek to Whitefish Lake, then directly across Whitefish Lake to Ophir Creek, then along the west bank of Ophir Creek to its headwaters at 61°10.22′ N lat., 159° 46.05″ W long., and the drainages flowing into the Bering Sea from Cape Newenham on the south to and including the Pastolik River drainage on the north; Nunivak, St. Matthews, and adjacent islands between Cape Newenham and the Pastolik River, and all seaward waters and lands within 3 miles of these coastlines.

(ii) In the Kalskag Controlled Use Area, which consists of that portion of Unit 18 bounded by a line from Lower Kalskag on the Kuskokwim River, northwesterly to Russian Mission on the Yukon River, then east along the north bank of the Yukon River to the old site of Paimiut, then back to Lower Kalskag, you are not allowed to use aircraft for hunting any ungulate, bear, wolf, or wolverine, including the transportation of any hunter and ungulate, bear, wolf, or wolverine part; however, this does not apply to transportation of a hunter or ungulate, bear, wolf, or wolverine part by aircraft between publicly owned airports in the Controlled Use Area or between a publicly owned airport within the Area and points outside the Area.

(iii) Unit-specific regulations:

(A) If you have a trapping license, you may use a firearm to take beaver in Unit 18 from April 1 through June 10.

(B) You may hunt brown bear by State registration permit in lieu of a resident tag if you have obtained a State registration permit prior to hunting.

(C) You may take caribou from a boat moving under power in Unit 18.

(D) You may take moose from a boat moving under power in that portion of Unit 18 west of a line running from the mouth of the Ishkowik River to the closest point of Dall Lake, then to the east bank of the Johnson River at its entrance into Nunavakanukakslak Lake (N 60°59.41′ Latitude; W 162°22.14′ Longitude), continuing upriver along a line ½ mile south and east of, and paralleling a line along the southerly bank of the Johnson River to the confluence of the east bank of Crooked Creek, then continuing upriver to the outlet at Arhymot Lake, then following the south bank west to the Unit 18 border.

(E) Taking of wildlife in Unit 18 while in possession of lead shot size T, .20 caliber or less in diameter, is prohibited.

(F) You may not pursue with a motorized vehicle an ungulate that is at or near a full gallop.

(G) You may use artificial light when taking a bear at a den site.

TABLE 18 TO PARAGRAPH (n)(18)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear: 1 bear by State registration permit only	Sep. 1–May 31.
Caribou:	
Unit 18, that portion to the east and south of the Kuskokwim River—up to 2 caribou by State registration permit.	Season may be announced between Aug. 1–Mar. 15.
Unit 18, remainder—up to 2 caribou by State registration permit	Season may be announced between Aug. 1–Mar. 15.
Moose: Unit 18, that portion east of a line running from the mouth of the Ishkowik River to the closest point of Dall Lake, then to the east bank of the Johnson River at its entrance into Nunavakanukakslak Lake (N 60°59.41′ Latitude; W162°22.14″ Longitude), continuing upriver along a line ½ mile south and east of, and paralleling a line along the southerly bank of the Johnson River to the confluence of the east bank of Crooked Creek, then continuing upriver to the outlet at Arhymot Lake, then following the south bank east of the Unit 18 border and then north of and including the Eek River drainage—1 antlered bull by State registration permit during the fall season.	Sep. 1–Oct. 15.
Or	
1 antlered bull by Federal registration permit during a may-be-announced winter season	May be announced between Dec. 1–Jan. 31.
Federal public lands are closed to the taking of moose except by residents of Tuntutuliak, Eek, Napakiak, Napaskiak, Kasigluk, Nunapitchuk, Atmautlauk, Oscarville, Bethel, Kwethluk, Akiachak, Akiak, Tuluksak, Lower Kalskag, and Kalskag.	
Unit 18, south of the Eek River drainage and north of the Goodnews River drainage—1 antlered bull by State registration permit.	Sep. 1–30.
Unit 18, Goodnews River drainage and south to the Unit 18 boundary—1 antlered bull by State registration permit.	Sep. 1–30.
or	
1 moose by State registration permit	A season may be announced between Dec. 1 and the last day of Feb.
Unit 18, remainder—3 moose, only one of which may be antlered. Antlered bulls may not be harvested from Oct. 1 through Nov. 30.	Aug. 1–Apr. 30.
Beaver: No limit	July 1–June 30.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Arctic (Blue and White Phase): 2 foxes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.
Hare:	
Snowshoe hare: No limit	July 1–June 30.
Alaska hare: 2 per day, 6 per season	Aug. 1–May 31.
Lynx: 5 lynx	Aug. 10–Apr. 30.
Wolf: 10 wolves	Aug. 10–Apr. 30.
Wolverine: 2 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce and Ruffed): 15 per day, 30 in possession	Aug. 10–Apr. 30.

TABLE 18 TO PARAGRAPH (n)(18)—Continued

Harvest limits	Open season
Ptarmigan (Rock and Willow): 15 per day, 30 in possession	Aug. 10–May 30.
Trapping	
Beaver: No limit	July 1–June 30.
Coyote: No limit	Nov. 10–Mar. 31.
Fox, Arctic (Blue and White Phase): No limit	Nov. 10–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 10–Mar. 31.
Lynx: No limit	Nov. 10–Mar. 31.
Marten: No limit	Nov. 10–Mar. 31.
Mink and Weasel: No limit	Nov. 10–Mar. 31.
Muskrat: No limit	Nov. 10–June 10.
Otter: No limit	Nov. 10–Mar. 31.
Wolf: No limit	Nov. 10–Mar. 31.
Wolverine: No limit	Nov. 10–Mar. 31.

(19) *Unit 19.* (i) Unit 19 consists of the Kuskokwim River drainage upstream, excluding the drainages of Arhymot Lake, from a line starting at the outlet of Arhymot Lake at Crooked Creek (locally known as Johnson River), then along the south bank of Crooked Creek downstream to the northern terminus of Crooked Creek to the Yukon-Kuskokwim Portage (locally known as the Mud Creek Tramway), then along the west side of the tramway to Mud Creek, then along the westerly bank of Mud Creek downstream to an unnamed slough of the Kuskokwim River (locally known as First Slough or Kalskag Slough), then along the west bank of this unnamed slough downstream to its confluence with the Kuskokwim River, then southeast across the Kuskokwim River to its southerly bank, then along the south bank of the Kuskokwim River upriver to the confluence of a Kuskokwim River slough locally known as Old River, then across Old River to the downriver terminus of the island formed by Old River and the Kuskokwim River, then along the north bank of the main channel of Old River to Igyalleq Creek (Whitefish Creek), then along the south and west bank of Igyalleq Creek to Whitefish Lake, then directly across Whitefish Lake to Ophir Creek then along the west bank of Ophir Creek to its headwaters at 61°10.22′ N lat., 159°46.05″ W long.:

(A) Unit 19A consists of the Kuskokwim River drainage downstream from and including the Moose Creek drainage on the north bank and downstream from and including the Stony River drainage on the south bank, excluding Unit 19B;

(B) Unit 19B consists of the Aniak River drainage upstream from and including the Salmon River drainage, the Holitna River drainage upstream from and including the Bakbuk Creek drainage, that area south of a line from the mouth of Bakbuk Creek to the radar dome at Sparrevohn Air Force Base, including the Hoholitna River drainage upstream from that line, and the Stony River drainage upstream from and including the Can Creek drainage;

(C) Unit 19C consists of that portion of Unit 19 south and east of a line from Benchmark M#1.26 (approximately 1.26 miles south of the northwestern corner of the original Mt. McKinley National Park boundary) to the peak of Lone Mountain, then due west to Big River, including the Big River drainage upstream from that line, and including the Swift River drainage upstream from and including the North Fork drainage; and

(D) Unit 19D consists of the remainder of Unit 19.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public land:

(A) You may not take wildlife for subsistence uses on lands within Mount McKinley National Park as it existed prior to December 2, 1980. Subsistence uses as authorized by this paragraph (n)(19) are permitted in Denali National Preserve and lands added to Denali National Park on December 2, 1980.

(B) In the Upper Kuskokwim Controlled Use Area, which consists of that portion of Unit 19D upstream from the mouth of the Selatna River, but excluding the Selatna and Black River drainages, to a line extending from Dyckman Mountain on the northern Unit 19D boundary southeast to the 1,610-foot crest of Munsatli Ridge, then south along Munsatli Ridge to the 2,981-foot peak of Telida Mountain, then northeast to the intersection of the western boundary of Denali National Preserve with the Minchumina-Telida winter trail, then south along the western boundary of Denali National Preserve to the southern boundary of Unit 19D, you may not use aircraft for hunting moose, including transportation of any moose hunter or moose part; however, this does not apply to transportation of a moose hunter or moose part by aircraft between publicly owned airports in the Controlled Use Area, or between a publicly owned airport within the area and points outside the area.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 30.

(B) You may hunt brown bear by State registration permit in lieu of a resident tag in those portions of Units 19A and 19B downstream of and including the Aniak River drainage if you have obtained a State registration permit prior to hunting.

(C) In Unit 19C, individual residents of Nikolai may harvest sheep during the Aug. 10 to Sep. 20 season and not have that animal count against the community harvest limit (during the Oct. 1 to Mar. 30 season). Individual residents of Nikolai that harvest a sheep under State regulations may not participate in the Oct. 1 to Mar. 30 community harvest.

TABLE 19 TO PARAGRAPH (n)(19)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear: Units 19A and 19B, those portions which are downstream of and including the Aniak River drainage—1 bear by State registration permit.	Aug. 10–June 30.
Units 19A, remainder, 19B, remainder, and Unit 19D—1 bear	Aug. 10–June 30.
Caribou: Units 19A and 19B (excluding rural Alaska residents of Lime Village)—up to 2 caribou by State registration permit.	Season may be announced between Aug. 1–Mar. 15.
Unit 19C—1 caribou	Aug. 10–Oct. 10.
Unit 19D, south and east of the Kuskokwim River and North Fork of the Kuskokwim River—1 caribou	Aug. 10–Sep. 30. Nov. 1–Jan. 31.
Unit 19D, remainder—1 caribou	Aug. 10–Sep. 30.
Unit 19, residents domiciled in Lime Village only—no individual harvest limit but a village harvest quota of 200 caribou; cows and calves may not be taken from Apr. 1 through Aug. 9. Reporting will be by a community reporting system..	July 1–June 30.
Sheep: 1 ram with [7] [8] curl horn or larger	Aug. 10–Sep. 20.
Unit 19C, that portion within the Denali National Park and Preserve-residents of Nikolai only—no individual harvest limit, but a community harvest quota will be set annually by the Denali National Park and Preserve Superintendent; rams or ewes without lambs only. Reporting will be by a community reporting system..	Oct. 1–Mar. 30.
Moose: Unit 19, residents of Lime Village only—no individual harvest limit, but a village harvest quota of 28 bulls (including those taken under the State permits). Reporting will be by a community reporting system..	July 1–June 30.
Unit 19A, Lime Village Management Area—2 bulls by State or Federal registration permit	Aug. 10–Sep. 25. Nov. 20–Mar 31.
Unit 19A, north of the Kuskokwim River, upstream from but excluding the George River drainage, and south of the Kuskokwim River upstream from and including the Downey Creek drainage, not including the Lime Village Management Area—1 antlered bull by State registration permit available in Sleetmute and Stoney River on July 24. Permits issued on a first come, first served basis (number of permits to be announced annually)..	Sep. 1–5.
Unit 19A, remainder—1 antlered bull by Federal drawing permit or a State permit. Federal public lands are closed to the taking of moose except by residents of Tuluksak, Lower Kalskag, Upper Kalskag, Aniak, Chuathbaluk, and Crooked Creek hunting under these regulations.	Sep. 1–20.
Unit 19B—1 bull with spike-fork or 50-inch antlers or antlers with 4 or more brow tines on one side	Sep. 1–20.
Unit 19C—1 antlered bull	Sep. 1–20.
Unit 19C—1 bull by State registration permit	Jan. 15–Feb. 15.
Unit 19D, that portion of the Upper Kuskokwim Controlled Use Area within the North Fork drainage upstream from the confluence of the South Fork to the mouth of the Swift Fork—1 antlered bull.	Sep. 1–30.
Unit 19D, remainder of the Upper Kuskokwim Controlled Use Area—1 bull	Sep. 1–30. Dec. 1–Feb. 28.
Unit 19D, remainder—1 antlered bull	Sep. 1–30. Dec. 1–15.
Coyote: 10 coyotes	Aug. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 1–Feb. 28.
Wolf: Unit 19D—10 wolves per day	Aug. 10–Apr. 30.
Unit 19, remainder—5 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce, Ruffed, and Sharp-tailed): 15 per day, 30 in possession	Aug. 10–Apr. 30.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver: No limit	Nov. 1–June 10.
Coyote: No limit	Nov. 1–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 1–Mar. 31.
Lynx: No limit	Nov. 1–Feb. 28.
Marten: No limit	Nov. 1–Feb. 28.
Mink and Weasel: No limit	Nov. 1–Feb. 28.
Muskrat: No limit	Nov. 1–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Nov. 1–Apr. 30.
Wolverine: No limit	Nov. 1–Mar. 31.

(20) *Unit 20.* (i) Unit 20 consists of the Yukon River drainage upstream from and including the Tozitna River drainage to and including the Hamlin Creek drainage, drainages into the south bank of the Yukon River upstream from and including the Charley River drainage, the Ladue River and Fortymile River drainages, and the Tanana River drainage north of Unit 13 and downstream from the east bank of the Robertson River:

(A) Unit 20A consists of that portion of Unit 20 bounded on the south by the Unit 13 boundary, bounded on the east by the west bank of the Delta River, bounded on the north by the north bank of the Tanana River from its confluence with the Delta River downstream to its confluence with the Nenana River, and

bounded on the west by the east bank of the Nenana River.

(B) Unit 20B consists of drainages into the northern bank of the Tanana River from and including Hot Springs Slough upstream to and including the Banner Creek drainage.

(C) Unit 20C consists of that portion of Unit 20 bounded on the east by the east bank of the Nenana River and on the north by the north bank of the Tanana River downstream from the Nenana River.

(D) Unit 20D consists of that portion of Unit 20 bounded on the east by the east bank of the Robertson River and on the west by the west bank of the Delta River, and drainages into the north bank of the Tanana River from its confluence with the Robertson River downstream to, but excluding, the Banner Creek drainage.

(E) Unit 20E consists of drainages into the south bank of the Yukon River upstream from and including the Charley River drainage, and the Ladue River drainage.

(F) Unit 20F consists of the remainder of Unit 20.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public land:

(A) You may not take wildlife for subsistence uses on lands within Mount McKinley National Park as it existed prior to December 2, 1980. Subsistence uses as authorized by this paragraph (n)(20) are permitted in Denali National Preserve and lands added to Denali National Park on December 2, 1980.

(B) You may not use motorized vehicles or pack animals for hunting Aug. 5–25 in the Delta Controlled Use Area, the boundary of which is defined as: a line beginning at the confluence of Miller Creek and the Delta River, then west to vertical angle benchmark Miller, then west to include all drainages of Augustana Creek and Black Rapids Glacier, then north and east to include all drainages of McGinnis Creek to its confluence with the Delta River, then east in a straight line across the Delta River to Mile 236.7 of the Richardson Highway, then north along the Richardson Highway to its junction with the Alaska Highway, then east along the Alaska Highway to the west bank of the Johnson River, then south along the west bank of the Johnson River and Johnson Glacier to the head of the Canwell Glacier, then west along the north bank of the Canwell Glacier and Miller Creek to the Delta River.

(C) You may not use firearms, snowmobiles, licensed highway vehicles or motorized vehicles, except aircraft and boats, in the Dalton Highway Corridor Management Area, which consists of those portions of Units 20, 24, 25, and 26 extending 5 miles from each side of the Dalton Highway from the Yukon River to milepost 300 of the Dalton Highway, except as follows: Residents living within the Dalton Highway Corridor Management Area may use snowmobiles only for the subsistence taking of wildlife. You may use licensed highway vehicles only on designated roads within the Dalton Highway Corridor Management Area. The residents of Alatna, Allakaket, Anaktuvuk Pass, Bettles, Evansville, Stevens Village, and residents living within the Corridor may use firearms within the Corridor only for subsistence taking of wildlife.

(D) You may not use any motorized vehicle for hunting August 5–September 20 in the Glacier Mountain Controlled Use Area, which consists of that portion of Unit 20E bounded by a line beginning at Mile 140 of the Taylor Highway, then north along the highway to Eagle, then west along the cat trail from Eagle to Crooked Creek, then from Crooked Creek southwest along the west bank of Mogul Creek to its headwaters on North Peak, then west across North Peak to the headwaters of Independence Creek, then southwest along the west bank of Independence Creek to its confluence with the North Fork of the Fortymile River, then easterly along the south bank of the North Fork of the Fortymile River to its confluence with Champion Creek, then across the North Fork of the Fortymile River to the south bank of Champion Creek and easterly along the south bank of Champion Creek to its confluence with Little Champion Creek, then northeast along the east bank of Little Champion Creek to its headwaters, then northeasterly in a direct line to Mile 140 on the Taylor Highway; however, this does not prohibit motorized access via, or transportation of harvested wildlife on, the Taylor Highway or any airport.

(E) You may by permit hunt moose on the Minto Flats Management Area, which consists of that portion of Unit 20 bounded by the Elliot Highway beginning at Mile 118, then northeasterly to Mile 96, then east to the Tolovana Hotsprings Dome, then east to the Winter Cat Trail, then along the Cat Trail south to the Old Telegraph Trail at Dunbar, then westerly along the trail to a point where it joins the Tanana River 3 miles above Old Minto, then along the north bank of the Tanana River (including all channels and sloughs except Swan Neck Slough), to the confluence of the Tanana and Tolovana Rivers and then northerly to the point of beginning.

(F) You may hunt moose only by bow and arrow in the Fairbanks Management Area. The Area consists of that portion of Unit 20B bounded by a line from the confluence of Rosie Creek and the Tanana River, northerly along Rosie Creek to Isberg Road, then northeasterly on Isberg Road to Cripple Creek Road, then northeasterly on Cripple Creek Road to the Parks Highway, then north on the Parks Highway to Alder Creek, then westerly to the middle fork of Rosie Creek through section 26 to the Parks Highway, then east along the Parks Highway to Alder Creek, then upstream along Alder Creek to its confluence with Emma Creek, then upstream along Emma Creek to its headwaters, then northerly along the hydrographic divide between Goldstream Creek drainages and Cripple Creek drainages to the summit of Ester Dome, then down Sheep Creek to its confluence with Goldstream Creek, then easterly along Goldstream Creek to Sheep Creek Road, then north on Sheep Creek Road to Murphy Dome Road, then west on Murphy Dome Road to Old Murphy Dome Road, then east on Old Murphy Dome Road to the Elliot Highway, then south on the Elliot Highway to Goldstream Creek, then easterly along Goldstream Creek to its confluence with First Chance Creek, Davidson Ditch, then southeasterly along the Davidson Ditch to its confluence with the tributary to Goldstream Creek in Section 29, then downstream along the tributary to its confluence with Goldstream Creek, then in a straight line to First Chance Creek, then up First Chance Creek to Tungsten Hill, then southerly along Steele Creek to its confluence with Ruby Creek, then upstream along Ruby Creek to Esro Road, then south on Esro Road to Chena Hot Springs Road, then east on Chena Hot Springs Road to Nordale Road, then south on Nordale Road to the Chena River, to its intersection with the Trans-Alaska Pipeline right of way, then southeasterly along the easterly edge of the Trans-Alaska Pipeline right of way to the Chena River, then along the north bank of the Chena River to the Moose Creek dike, then southerly along the Moose Creek dike to its intersection with the Tanana River, and then westerly along the north bank of the Tanana River to the point of beginning.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear April 15–June 30; you may use bait to hunt wolves on FWS and BLM lands.

(B) You may not use a steel trap or a snare using cable smaller than 3/32-inch diameter to trap coyotes or wolves in Unit 20E during April and October.

(C) Residents of Units 20 and 21 may take up to three moose per regulatory year for the celebration known as the Nuchalawoyya Potlatch, under the terms of a Federal registration permit. Permits will be issued to individuals at the request of the Native Village of Tanana only. This three-moose limit is not cumulative with that permitted by the State.

TABLE 20 TO PARAGRAPH (n)(20)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear: Unit 20A—1 bear	Sep. 1–May 31.
Unit 20E—1 bear	Aug. 10–June 30.
Unit 20, remainder—1 bear	Sep. 1–May 31.
Caribou: Unit 20E—up to 3 caribou, to be announced, by a joint State/Federal registration permit	Fall season between Aug. 1 and Sep. 30, to be announced. Winter season between Oct. 21 and Mar. 31, to be announced.
Unit 20F, north of the Yukon River—1 caribou	Aug. 10–Mar. 31.
Unit 20F, east of the Dalton Highway and south of the Yukon River—up to 3 caribou, to be announced, by a joint State/Federal registration permit.	Fall season between Aug. 1 and Sep. 30, to be announced. Winter season between Oct. 21 and Mar. 31, to be announced.
Moose: Unit 20A—1 antlered bull	Sep. 1–20.
Unit 20B—1 antlered bull	Sep. 1–20.
Unit 20C, that portion within Denali National Park and Preserve west of the Toklat River, excluding lands within Mount McKinley National Park as it existed prior to December 2, 1980—1 antlered bull; however, white-phased or partial albino (more than 50 percent white) moose may not be taken.	Sep. 1–30. Nov. 15–Dec. 15.
Unit 20C, remainder—1 antlered bull; however, white-phased or partial albino (more than 50 percent white) moose may not be taken.	Sep. 1–30.
Unit 20E, that portion within Yukon-Charley Rivers National Preserve—1 bull	Aug. 20–Sep. 30.
Unit 20E, that portion drained by the Middle Fork of the Fortymile River upstream from and including the Joseph Creek drainage—1 bull.	Aug. 20–Sep. 30.
Unit 20E, remainder—1 bull by joint Federal/State registration permit	Aug. 20–Sep. 30.
Unit 20F, that portion within the Dalton Highway Corridor Management Area—1 antlered bull by Federal registration permit only.	Sep. 1–25.
Unit 20F, remainder—1 antlered bull	Sep. 1–30. Dec. 1–10.
Sheep: Unit 20E—1 ram with full-curl horn or larger	Aug. 10–Sep. 20.
Unit 20, remainder	No open season.
Beaver: Unit 20E—Yukon-Charley Rivers National Preserve—6 beaver per season. Meat from harvested beaver must be salvaged for human consumption.	Sep. 20–May 15.
Coyote: 10 coyotes	Aug. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: Units 20A, 20B, and that portion of 20C east of the Teklanika River—2 lynx	Dec. 1–Jan. 31.
Unit 20E—2 lynx	Nov. 1–Jan. 31.
Unit 20, remainder—2 lynx	Dec. 1–Jan. 31.
Muskrat: Unit 20E, that portion within Yukon-Charley Rivers National Preserve—No limit	Sep. 20–June 10.
Unit 20C, that portion within Denali National Park and Preserve—25 muskrat	Nov. 1–June 10.
Unit 20, remainder	No open season.
Wolf: Unit 20—10 wolves	Aug. 10–Apr. 30.
Unit 20C, that portion within Denali National Park and Preserve—1 wolf during the Aug. 10–Oct. 31 period; 5 wolves during the Nov. 1–Apr. 30 period, for a total of 6 wolves for the season.	Aug. 10–Oct. 31. Nov. 1–Apr. 30.
Unit 20C, remainder—10 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce, Ruffed, and Sharp-tailed): Units 20A, 20B, 20C, 20E, and 20F—15 per day, 30 in possession	Aug. 10–Mar. 31.
Ptarmigan (Rock and Willow): Unit 20, those portions within 5 miles of Alaska Route 5 (Taylor Highway, both to Eagle and the Alaska-Canada boundary) and that portion of Alaska Route 4 (Richardson Highway) south of Delta Junction—20 per day, 40 in possession.	Aug. 10–Mar. 31.
Unit 20, remainder—20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver: Units 20A, 20B, 20C, and 20F—No limit	Nov. 1–Apr. 15.
Unit 20E—No limit. Hide or meat must be salvaged. Traps, snares, bow and arrow, or firearms may be used	Sep. 15–June 10.
Coyote: Unit 20E—No limit	Oct. 15–Apr. 30.
Unit 20, remainder—No limit	Nov. 1–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 1–Feb. 28.
Lynx: Unit 20A, 20B, and 20C east of the Teklanika River—No limit	Dec. 15–Feb. 15.
Unit 20E—No limit	Nov. 1–Mar. 15.
Unit 20F and 20C, remainder—No limit	Nov. 1–Feb. 28.
Marten: No limit	Nov. 1–Feb. 28.

TABLE 20 TO PARAGRAPH (n)(20)—Continued

Harvest limits	Open season
Mink and Weasel: No limit	Nov. 1–Feb. 28.
Muskrat: Unit 20E—No limit	Sep. 20–June 10.
Unit 20, remainder—No limit	Nov. 1–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: Units 20A, 20B, 20C, and 20F—No limit	Nov. 1–Apr. 30.
Unit 20E—No limit	Oct. 1–Apr. 30.
Wolverine: No limit	Nov. 1–Feb. 28.

(21) *Unit 21.* (i) Unit 21 consists of drainages into the Yukon River and Arhymot Lake upstream from a line starting at the downriver boundary of Paimiut on the north bank of the Yukon River then south across the Yukon River to the northern terminus of the Paimiut Portage, then south along the Portage to its intersection with Arhymot Lake, then south along the northern and western bank of Arhymot Lake to the outlet at Crooked Creek (locally known as Johnson River) drainage then to, but not including, the Tozitna River drainage on the north bank, and to but not including the Tanana River drainage on the south bank, and excluding the Koyukuk River drainage upstream from the Dulbi River drainage:

(A) Unit 21A consists of the Innoko River drainage upstream from and including the Iditarod River drainage.

(B) Unit 21B consists of the Yukon River drainage upstream from Ruby and east of the Ruby-Poorman Road, downstream from and excluding the Tozitna River and Tanana River drainages, and excluding the Melozitna River drainage upstream from Grayling Creek.

(C) Unit 21C consists of the Melozitna River drainage upstream from Grayling Creek, and the Dulbi River drainage upstream from and including the Cottonwood Creek drainage.

(D) Unit 21D consists of the Yukon River drainage from and including the Blackburn Creek drainage upstream to Ruby, including the area west of the Ruby-Poorman Road, excluding the Koyukuk River drainage upstream from the Dulbi River drainage, and excluding the Dulbi River drainage upstream from Cottonwood Creek.

(E) Unit 21E consists of that portion of Unit 21 in the Yukon River and Arhymot Lake drainages upstream from a line starting at the downriver boundary of Paimiut on the north bank of the Yukon River, then south across the Yukon River to the northern terminus of the Paimiut Portage, then south along the Portage to its intersection with Arhymot Lake, then along the northern and western bank of Arhymot Lake to the outlet at Crooked Creek (locally known as Johnson River) drainage, then to, but not including, the Blackburn Creek drainage, and the Innoko River drainage downstream from the Iditarod River drainage.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public land:

(A) The Koyukuk Controlled Use Area, which consists of those portions of Units 21 and 24 bounded by a line from the north bank of the Yukon River at Koyukuk at 64°52.58′ N lat., 157°43.10″ W long., then northerly to the confluences of the Honhosa and Kateel Rivers at 65°28.42′ N lat., 157°44.89″ W long., then northeasterly to the confluences of Billy Hawk Creek and the Huslia River (65°57′ N lat., 156°41″ W long.) at 65°56.66′ N lat., 156°40.81″ W long., then easterly to the confluence of the forks of the Dakli River at 66°02.56′ N lat., 156° 12.71″ W long., then easterly to the confluence of McLanes Creek and the Hogatza River at 66°00.31′ N lat., 155°18.57″ W long., then southwesterly to the crest of Hochandochtla Mountain at 65°31.87′ N lat., 154°52.18″ W long., then southwest to the mouth of Cottonwood Creek at 65°3.00′ N lat., 156°06.43″ W long., then southwest to Bishop Rock (Yistletaw) at 64°49.35′ N lat., 157°21.73″ W long., then westerly along the north bank of the Yukon River (including Koyukuk Island) to the point of beginning, is closed during moose hunting seasons to the use of aircraft for hunting moose, including transportation of any moose hunter or moose part; however, this does not apply to transportation of a moose hunter or moose part by aircraft between publicly owned airports in the controlled use area or between a publicly owned airport within the area and points outside the area; all hunters on the Koyukuk River passing the ADF&G-operated check station at Ella's Cabin (15 miles upstream from the Yukon on the Koyukuk River) are required to stop and report to ADF&G personnel at the check station.

(B) The Paradise Controlled Use Area, which consists of that portion of Unit 21 bounded by a line beginning at the old village of Paimiut, then north along the west bank of the Yukon River to Paradise, then northwest to the mouth of Stanstrom Creek on the Bonasila River, then northeast to the mouth of the Anvik River, then along the west bank of the Yukon River to the lower end of Eagle Island (approximately 45 miles north of Grayling), then to the mouth of the Iditarod River, then extending 2 miles easterly down the east bank of the Innoko River to its confluence with Paimiut Slough, then south along the east bank of Paimiut Slough to its mouth, and then to the old village of Paimiut, is closed during moose hunting seasons to the use of aircraft for hunting moose, including transportation of any moose hunter or part of moose; however, this does not apply to transportation of a moose hunter or part of moose by aircraft between publicly owned airports in the Controlled Use Area or between a publicly owned airport within the area and points outside the area.

(iii) In Unit 21D, you may hunt brown bear by State registration permit in lieu of a resident tag if you have obtained a State registration permit prior to hunting. Aircraft may not be used in any manner for brown bear hunting under the authority of a brown bear State registration permit, including transportation of hunters, bears, or parts of bears; however, this does not apply to transportation of bear hunters or bear parts by regularly scheduled flights to and between communities by carriers that normally provide scheduled service to this area, nor does it apply to transportation of aircraft to or between publicly owned airports.

(iv) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 30; and in the Koyukuk Controlled Use Area, you may also use bait to hunt black bear between September 1 and September 25.

(B) If you have a trapping license, you may use a firearm to take beaver in Unit 21(E) from Nov. 1 through June 10.

(C) The residents of Units 20 and 21 may take up to three moose per regulatory year for the celebration known as the Nuchalawoyya Potlatch, under the terms of a Federal registration

permit. Permits will be issued to individuals only at the request of the Native Village of Tanana. This three-moose limit is not cumulative with that permitted by the State.

(D) The residents of Unit 21 may take up to three moose per regulatory year for the celebration known as the Kaltag/Nulato Stickdance, under the terms of a Federal registration permit. Permits will be issued to individuals only at the request of the Native Village of Kaltag or Nulato. This three-moose limit is not cumulative with that permitted by the State.

TABLE 21 TO PARAGRAPH (n)(21)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear:	
Unit 21D—1 bear by State registration permit only	Aug. 10–June 30.
Unit 21, remainder—1 bear	Aug. 10–June 30.
Caribou:	
Unit 21A—1 caribou	Aug. 10–Sep. 30. Dec. 10–20.
Unit 21B, that portion north of the Yukon River and downstream from Ukawutni Creek	No open season.
Unit 21C, the Dulbi and Melozitna River drainages downstream from Big Creek	No open season.
Unit 21B, remainder, Unit 21C, remainder, and Unit 21E—1 caribou	Aug. 10–Sep. 30.
Unit 21D, north of the Yukon River and east of the Koyukuk River—caribou may be taken during a winter season to be announced.	Winter season to be announced.
Unit 21D, remainder—5 caribou per day, as follows: Calves may not be taken	
Bulls may be harvested	July 1–Oct. 14. Feb. 1–June 30.
Cows may be harvested	Sep. 1–Mar. 31.
Moose:	
Unit 21B, that portion within the Nowitna National Wildlife Refuge downstream from and including the Little Mud River drainage—1 bull. A State registration permit is required Sep. 5–25. A Federal registration permit is required Sep. 26–Oct. 1.	Sep. 5–Oct. 1.
Unit 21B, that portion within the Nowitna National Wildlife Refuge downstream from and including the Little Mud River drainage—1 antlered bull. A Federal registration permit is required during the 5-day season and will be limited to one per household.	Five-day season to be announced between Dec. 1 and Mar. 31.
Units 21A and 21B, remainder—1 bull	Aug. 20–Sep. 25. Nov. 1–30.
Unit 21C—1 antlered bull	Sep. 5–25.
Unit 21D, Koyukuk Controlled Use Area—1 bull by State registration permit; 1 antlerless moose by Federal permit if authorized by announcement by the Koyukuk/Nowitna/Innoko NWR manager. Harvest of cow moose accompanied by calves is prohibited. A harvestable surplus of cows will be determined for a quota.	Sep. 1–25. Mar. 1–5 season to be announced.
or	
1 antlered bull by Federal permit, if there is no Mar. 1–5 season and if authorized by announcement by the Koyukuk/Nowitna/Innoko NWR manager and BLM Central Yukon field office manager.	Apr. 10–15 season to be announced.
Unit 21D, that portion south of the south bank of the Yukon River, downstream of the up-river entrance of Kala Slough and west of Kala Creek—1 moose by State registration permit.	Aug. 22–31. Sep. 5–25.
Antlerless moose may be taken only during Sep. 21–25 season if authorized jointly by the Koyukuk/Nowitna/Innoko NWR Manager and the BLM Central Yukon Field Office Manager. Antlerless moose may be harvested during any of the winter seasons. Harvest of cow moose accompanied by calves is prohibited.	Mar. 1–31 season may be announced.
Unit 21D, remainder—1 moose by State registration permit. Antlerless moose may be taken only during Sep. 21–25 and the Mar. 1–5 season if authorized jointly by the Koyukuk/Nowitna/Innoko NWR Manager and the BLM Central Yukon Field Office Manager. Harvest of cow moose accompanied by calves is prohibited. During the Aug. 22–31 and Sep. 5–25 seasons, a State registration permit is required. During the Mar. 1–5 season, a Federal registration permit is required.	Aug. 22–31. Sep. 5–25. Mar. 1–5 season to be announced.
Unit 21E—1 moose; however, only bulls may be taken Aug. 25–Sep. 30	Aug. 25–Sep. 30.
During the Feb. 15–Mar. 15 season, a Federal registration permit is required. The permit conditions and any needed closures for the winter season will be announced by the Innoko NWR manager after consultation with the ADF&G area biologist and the Chairs of the Western Interior Regional Advisory Council and the Middle Yukon Fish and Game Advisory Committee as stipulated in a letter of delegation. Moose may not be taken within one-half mile of the Innoko or Yukon Rivers during the winter season.	Feb. 15–Mar. 15.
Beaver:	
Unit 21E—No limit	Nov. 1–June 10.
Unit 21, remainder	No open season.
Coyote: 10 coyotes	Aug. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.
Hare (Snowshoe and Tundra): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 1–Feb. 28.
Wolf: 5 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce, Ruffed, and Sharp-tailed): 15 per day, 30 in possession	Aug. 10–Apr. 30.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver: No Limit	Nov. 1–June 10.

TABLE 21 TO PARAGRAPH (n)(21)—Continued

Harvest limits	Open season
Coyote: No limit	Nov. 1–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 1–Feb. 28.
Lynx: No limit	Nov. 1–Feb. 28.
Marten: No limit	Nov. 1–Feb. 28.
Mink and Weasel: No limit	Nov. 1–Feb. 28.
Muskrat: No limit	Nov. 1–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Nov. 1–Apr. 30.
Wolverine: No limit	Nov. 1–Mar. 31.

(22) *Unit 22*. (i) Unit 22 consists of Bering Sea, Norton Sound, Bering Strait, Chukchi Sea, and Kotzebue Sound drainages from, but excluding, the Pastolik River drainage in southern Norton Sound to, but not including, the Goodhope River drainage in Southern Kotzebue Sound, and all adjacent islands in the Bering Sea between the mouths of the Goodhope and Pastolik Rivers:

(A) Unit 22A consists of Norton Sound drainages from, but excluding, the Pastolik River drainage to, and including, the Ungalik River drainage, and Stuart and Besboro Islands.

(B) Unit 22B consists of Norton Sound drainages from, but excluding, the Ungalik River drainage to, and including, the Topkok Creek drainage.

(C) Unit 22C consists of Norton Sound and Bering Sea drainages from, but excluding, the Topkok Creek drainage to, and including, the Tisuk River drainage, and King and Sledge Islands.

(D) Unit 22D consists of that portion of Unit 22 draining into the Bering Sea north of, but not including, the Tisuk River to and including Cape York and St. Lawrence Island.

(E) Unit 22E consists of Bering Sea, Bering Strait, Chukchi Sea, and Kotzebue Sound drainages from Cape York to, but excluding, the Goodhope River drainage, and including Little Diomede Island and Fairway Rock.

(ii) You may hunt brown bear by State registration permit in lieu of a resident tag if you have obtained a State registration permit prior to hunting. Aircraft may not be used in any manner for brown bear hunting under the authority of a brown bear State registration permit, including transportation of hunters, bears, or parts of bears; however, this does not apply to transportation of bear hunters or bear parts by regularly scheduled flights to and between communities by carriers that normally provide scheduled service to this area, nor does it apply to transportation of aircraft to or between publicly owned airports.

(iii) Unit-specific regulations:

(A) If you have a trapping license, you may use a firearm to take beaver in Unit 22 during the established seasons.

(B) Coyote, incidentally taken with a trap or snare, may be used for subsistence purposes.

(C) A snowmachine may be used to position a hunter to select individual caribou for harvest provided that the animals are not shot from a moving snowmachine.

(D) The taking of one bull moose and up to three musk oxen by the community of Wales is allowed for the celebration of the Kingikmuit Dance Festival under the terms of a Federal registration permit. Permits will be issued to individuals only at the request of the Native Village of Wales. The harvest may occur only within regularly established seasons in Unit 22E. The harvest will count against any established quota for the area.

(E) A federally qualified subsistence user (recipient) may designate another federally qualified subsistence user to take musk oxen on his or her behalf. The designated hunter must get a designated hunter permit and must return a completed harvest report. The designated hunter may hunt for any number of recipients in the course of a season, but have no more than two harvest limits in his/her possession at any one time, except in Unit 22E where a resident of Wales or Shishmaref acting as a designated hunter may hunt for any number of recipients, but have no more than four harvest limits in his/her possession at any one time.

TABLE 22 TO PARAGRAPH (n)(22)

Harvest limits	Open season
Hunting	
Black Bear:	
Units 22A and 22B—3 bears	July 1–June 30.
Unit 22, remainder	No open season.
Brown Bear:	
Units 22A, 22D remainder, and 22E—1 bear by State registration permit only	Aug. 1–May 31.
Unit 22B—2 bears by State registration permit	Aug. 1–May 31.
Unit 22C—1 bear by State registration permit only	Aug. 1–Oct. 31. Apr. 1–May 31.
Unit 22D, that portion west of the Tisuk River drainage, west of the west bank of the unnamed creek originating at the Unit boundary opposite the headwaters of McAdam's Creek and west of the west bank of Canyon Creek to its confluence with Tuksuk Channel—2 bears by Federal registration permit.	July 1–June 30.
Caribou:	
Unit 22B, that portion west of Golovnin Bay and west of a line along the west bank of the Fish and Niukluk Rivers to the mouth of the Libby River, and excluding all portions of the Niukluk River drainage upstream from and including the Libby River drainage—5 caribou per day by State registration permit. Calves may not be taken.	Oct. 1–Apr. 30. May 1–Sep. 30, a season may be announced.

TABLE 22 TO PARAGRAPH (n)(22)—Continued

Harvest limits	Open season
Units 22A, that portion north of the Golsovia River drainage, 22B remainder, that portion of Unit 22D in the Kuzitrin River drainage (excluding the Pilgrim River drainage), and the Agiapuk River drainages, including the tributaries, and Unit 22E, that portion east of and including the Tin Creek drainage—5 caribou per day by State registration permit. Calves may not be taken.	July 1–June 30.
Unit 22A, remainder—5 caribou per day by State registration permit. Calves may not be taken	July 1–June 30, season may be announced.
Unit 22D, that portion in the Pilgrim River drainage—5 caribou per day by State registration permit. Calves may not be taken.	Oct. 1–Apr. 30. May 1–Sep. 30, season may be announced.
Units 22C, 22D remainder, 22E remainder—5 caribou per day by State registration permit. Calves may not be taken.	July 1–June 30, season may be announced.
Moose:	
Unit 22A, that portion north of the Egavik Creek drainage—1 bull. Federal public lands are closed to hunting Sep. 21–Aug. 31 except by federally qualified users hunting under these regulations.	Aug. 1–Sep. 30.
Unit 22A, that portion in the Unalakleet drainage and all drainages flowing into Norton Sound north of the Golsovia River drainage and south of and including the Egavik Creek drainage—1 bull by Federal registration permit. Federal public lands are closed to the taking of moose except by federally qualified users hunting under these regulations. The BLM Anchorage Field Office is delegated authority to close the season in consultation with ADF&G.	Aug. 15–Sep. 14.
Unit 22A, remainder—1 bull. However, during the period Jan.1–Feb. 15, only an antlered bull may be taken. Federal public lands are closed to the taking of moose, Oct. 1–Aug. 31, except by federally qualified subsistence users.	Aug. 1–Sep. 30. Jan. 1–Feb. 15.
Unit 22B, west of the Darby Mountains—1 bull by State registration permit. Quotas and any needed closures will be announced by the Anchorage Field Office Manager of the BLM, in consultation with NPS and ADF&G..	Sep. 1–14.
Federal public lands are closed to the taking of moose except by federally qualified subsistence users hunting under these regulations.	
Unit 22B, west of the Darby Mountains—1 bull by either Federal or State registration permit. Quotas and any needed season closures will be announced by the Anchorage Field Office Manager of the BLM, in consultation with NPS and ADF&G. Federal public lands are closed to the taking of moose except by residents of White Mountain and Golovin hunting under these regulations.	Jan. 1–31.
Unit 22B, remainder—1 bull	Aug. 1–Jan. 31.
Unit 22C—1 antlered bull	Sep. 1–14.
Unit 22D, that portion within the Kougarok, Kuzitrin, and Pilgrim River drainages—1 bull by State registration permit. Quotas and any needed closures will be announced by the Anchorage Field Office Manager of the BLM, in consultation with NPS and ADF&G. Federal public lands are closed to the taking of moose except by residents of Units 22D and 22C hunting under these regulations.	Sep. 1–14.
Unit 22D, that portion west of the Tisuk River drainage and Canyon Creek—1 bull by State registration permit. Quotas and any needed closures will be announced by the Anchorage Field Office Manager of the BLM, in consultation with NPS and ADF&G..	Sep. 1–14.
Unit 22D, that portion west of the Tisuk River drainage and Canyon Creek—1 bull by Federal registration permit. Quotas and any needed closures will be announced by the Anchorage Field Office Manager of the BLM, in consultation with NPS and ADF&G. Federal public lands are closed to the taking of moose except by residents of Units 22D and 22C hunting under these regulations.	Dec. 1–31.
Unit 22D, remainder—1 bull by State registration permit. Federal public lands are closed to the harvest of moose except by federally qualified subsistence users.	Aug. 10–Sep. 14.
Unit 22D, remainder—1 antlered bull by State registration permit. Federal public lands are closed to the harvest of moose except by federally qualified subsistence users.	Season may be announced, Dec. 1–Jan. 31.
Unit 22E—1 antlered bull. Federal public lands are closed to the taking of moose except by federally qualified subsistence users hunting under these regulations.	Aug. 1–Mar. 15.
Musk ox:	
Unit 22B—1 bull by Federal permit or State permit. Federal public lands are closed to the taking of musk ox except by federally qualified subsistence users hunting under these regulations.	Aug. 1–Mar. 15.
Unit 22D, that portion west of the Tisuk River drainage and Canyon Creek—1 bull by Federal permit or State permit. Federal public lands are closed to the harvest of musk ox except by residents of Nome and Teller hunting under these regulations.	Sep. 1–Mar. 15.
Unit 22D, that portion within the Kuzitrin River drainages—1 bull by Federal permit or State permit. Federal public lands are closed to the taking of musk ox except for residents of Council, Golovin, White Mountain, Nome, Teller, and Brevig Mission hunting under these regulations.	Aug. 1–Mar. 15.
Unit 22D, remainder—1 bull by Federal permit or State permit. Federal public lands are closed to the taking of musk ox except by residents of Elim, White Mountain, Nome, Teller, and Brevig Mission hunting under these regulations.	Aug. 1–Mar. 15.
Unit 22E—1 bull by Federal permit or State permit. Federal public lands are closed to the harvest of musk ox except by federally qualified subsistence users hunting under these regulations.	Aug. 1–Mar. 15.
Unit 22, remainder	No open season.
Beaver:	
Units 22A, 22B, 22D, and 22E—50 beaver	Nov. 1–June 10.
Unit 22, remainder	No open season.
Coyote	No open season.
Fox, Arctic (Blue and White Phase): 2 foxes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes	Nov. 1–Apr. 15.
Hare:	

TABLE 22 TO PARAGRAPH (n)(22)—Continued

Harvest limits	Open season
Snowshoe hare: No limit	Sep. 1–Apr. 15.
Alaska hare: 2 per day, 6 per season	Aug. 1–May 31.
Lynx: 2 lynx	Nov. 1–Apr. 15.
Marten:	
Units 22A and 22B—No limit	Nov. 1–Apr. 15.
Unit 22, remainder	No open season.
Mink and Weasel: No limit	Nov. 1–Jan. 31.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Nov. 1–Apr. 15.
Wolverine: 3 wolverines	Sep. 1–Mar. 31.
Grouse (Spruce): 15 per day, 30 in possession	Aug. 10–Apr. 30.
Ptarmigan (Rock and Willow):	
Units 22A and 22B east of and including the Niukluk River drainage—40 per day, 80 in possession	Aug. 10–Apr. 30.
Unit 22E—20 per day, 40 in possession	July 15–May 15.
Unit 22, remainder—20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver:	
Units 22A, 22B, 22D, and 22E—50 beaver	Nov. 1–June 10.
Unit 22C	No open season.
Coyote	No open season.
Fox, Arctic (Blue and White Phase): No limit	Nov. 1–Apr. 15.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 1–Apr. 15.
Lynx: No limit	Nov. 1–Apr. 15.
Marten: No limit	Nov. 1–Apr. 15.
Mink and Weasel: No limit	Nov. 1–Jan. 31.
Muskrat: No limit	Nov. 1–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Nov. 1–Apr. 30.
Wolverine: No limit	Nov. 1–Apr. 15.

(23) *Unit 23*. (i) Unit 23 consists of Kotzebue Sound, Chukchi Sea, and Arctic Ocean drainages from and including the Goodhope River drainage to Cape Lisburne.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public land:

(A) You may not use aircraft in any manner either for hunting of ungulates, bear, wolves, or wolverine, or for transportation of hunters or harvested species in the Noatak Controlled Use Area for the period August 15–September 30. The Area consists of that portion of Unit 23 in a corridor extending 5 miles on either side of the Noatak River beginning at the mouth of the Noatak River, and extending upstream to the mouth of Sapun Creek. This closure does not apply to the transportation of hunters or parts of ungulates, bear, wolves, or wolverine by regularly scheduled flights to communities by carriers that normally provide scheduled air service.

(B) [Reserved]

(iii) You may not use aircraft in any manner for brown bear hunting, including transportation of hunters, bears, or parts of bears; however, this does not apply to transportation of bear hunters or bear parts by regularly scheduled flights to and between communities by carriers that normally provide scheduled service to this area, nor does it apply to transportation of aircraft to or between publicly owned airports.

(iv) Unit-specific regulations:

(A) You may take caribou while hunting from a boat moving under power in Unit 23.

(B) In addition to other restrictions on method of take found in this section, you may also take swimming caribou with a firearm using rimfire cartridges.

(C) If you have a trapping license, you may take beaver with a firearm in all of Unit 23 from Nov. 1 through June 10.

(D) For the Baird and DeLong Mountain sheep hunts—a federally qualified subsistence user (recipient) may designate another federally qualified subsistence user to take sheep on his or her behalf. The designated hunter must obtain a designated hunter permit and must return a completed harvest report. The designated hunter may hunt for only one recipient in the course of a season and may have both his and the recipients' harvest limits in his/her possession at the same time.

(E) A snowmachine may be used to position a hunter to select individual caribou for harvest provided that the animals are not shot from a moving snowmachine. On BLM-managed lands only, a snowmachine may be used to position a caribou, wolf, or wolverine for harvest provided that the animals are not shot from a moving snowmachine.

(F) A federally qualified subsistence user (recipient) may designate another federally qualified subsistence user to take musk oxen on his or her behalf. The designated hunter must get a designated hunter permit and must return a completed harvest report. The designated hunter may hunt for any number of recipients but have no more than two harvest limits in his/her possession at any one time.

TABLE 23 TO PARAGRAPH (n)(23)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear: Unit 23—2 bears by State subsistence registration permit	July 1–June 30.
Caribou:	
Unit 23, that portion which includes all drainages north and west of, and including, the Singoalik River drainage—5 caribou per day by State registration permit as follows:.	
Bulls may be harvested	July 1–June 30.
Cows may be harvested. However, cows accompanied by calves may not be taken July 15–Oct. 14	July 15–Apr. 30.
Unit 23, remainder—5 caribou per day by State registration permit, as follows:.	
Bulls may be harvested	July 1–June 30.
Cows may be harvested. However, cows accompanied by calves may not be taken July 31–Oct. 14	July 31–Mar. 31.
Federal public lands within a 10-mile-wide corridor (5 miles either side) along the Noatak River from the western boundary of Noatak National Preserve upstream to the confluence with the Cutler River; within the northern and southern boundaries of the Eli and Agashashok River drainages, respectively; and within the Squirrel River drainage are closed to caribou hunting except by federally qualified subsistence users hunting under these regulations..	
Sheep:	
Unit 23, south of Rabbit Creek, Kiyak Creek, and the Noatak River, and west of the Cutler and Redstone Rivers (Baird Mountains)—1 sheep by Federal registration permit. Federal public lands are closed to the taking of sheep except by federally qualified subsistence users hunting under these regulations.	May be announced.
Unit 23, north of Rabbit Creek, Kiyak Creek, and the Noatak River, and west of the Aniuk River (DeLong Mountains)—1 sheep by Federal registration permit.	May be announced.
Unit 23, remainder (Schwatka Mountains) except for that portion within Gates of the Arctic National Park and Preserve—1 sheep by Federal registration permit.	May be announced.
Unit 23, remainder (Schwatka Mountains), that portion within Gates of the Arctic National Park and Preserve—1 ram with 7/8 curl or larger horn.	Aug. 10–Sep. 20.
Unit 23, remainder (Schwatka Mountains), that portion within Gates of the Arctic National Park and Preserve—1 sheep.	Oct. 1–Apr. 30.
Moose:	
Unit 23, that portion north and west of and including the Singoalik River drainage, and all lands draining into the Kukpuk and Ipewik Rivers—1 antlered bull.	July 1–Dec. 31.
No person may take a calf.	
Unit 23, remainder—1 antlered bull	Aug. 1–Dec. 31.
No person may take a calf.	
Musk ox:	
Unit 23, south of Kotzebue Sound and west of and including the Buckland River drainage—1 bull by Federal permit or State permit.	Aug. 1–Mar. 15.
Federal public lands are closed to the taking of musk oxen except by federally qualified subsistence users hunting under these regulations.	
Unit 23, Cape Krusenstern National Monument—1 bull by Federal permit	Aug. 1–Mar. 15.
Unit 23, that portion north and west of the Kobuk River drainage—1 bull by State or Federal registration permit.	Aug. 1–Mar. 15
Unit 23, remainder	No open season.
Beaver: No limit	July 1–June 30.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Arctic (Blue and White Phase): No limit	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): No limit	Sep. 1–Mar. 15.
Hare:	
Snowshoe hare: No limit	July 1–June 30.
Alaska hare: 2 per day, 6 per season	Aug. 1–May 31.
Lynx: 2 lynx	Nov. 1–Apr. 15.
Wolf: 15 wolves	Oct. 1–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Muskrat: No limit	July 1–June 30.
Grouse (Spruce and Ruffed): 15 per day, 30 in possession	Aug. 10–Apr. 30.
Ptarmigan (Rock, Willow, and White-tailed): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver: No limit	July 1–June 30.
Coyote: No limit	Nov. 1–Apr. 15.
Fox, Arctic (Blue and White Phase): No limit	Nov. 1–Apr. 15.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 1–Apr. 15.
Lynx: No limit	Nov. 1–Apr. 15.
Marten: No limit	Nov. 1–Apr. 15.
Mink and Weasel: No limit	Nov. 1–Jan. 31.
Muskrat: No limit	Nov. 1–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Nov. 1–Apr. 30.
Wolverine: No limit	Nov. 1–Apr. 15.

(24) *Unit 24.* (i) Unit 24 consists of the Koyukuk River drainage upstream from but not including the Dulbi River drainage:

(A) Unit 24A consists of the Middle Fork of the Koyukuk River drainage upstream from but not including the Harriet Creek and North Fork Koyukuk River drainages, to the South Fork of the Koyukuk River drainage upstream from Squaw Creek, the Jim River Drainage, the Fish Creek drainage upstream from and including the Bonanza Creek drainage, to the 1,410 ft. peak of the hydrologic divide with the northern fork of the Kanuti Chalatna River at N lat. 66°33.303′ W long. 151°03.637′ and following the unnamed northern fork of the Kanuti Chalatna Creek to the confluence of the southern fork of the Kanuti Chalatna River at N lat. 66°27.090′ W long. 151°23.841′, 4.2 miles SSW (194 degrees true) of Clawanmenka Lake and following the unnamed southern fork of the Kanuti Chalatna Creek to the hydrologic divide with the Kanuti River drainage at N lat. 66°19.789′ W long. 151°10.102′, 3.0 miles ENE (79 degrees true) from the 2,055 ft. peak on that divide, and the Kanuti River drainage upstream from the confluence of an unnamed creek at N lat. 66°13.050′ W long. 151°05.864′, 0.9 miles SSE (155 degrees true) of a 1,980 ft. peak on that divide, and following that unnamed creek to the Unit 24 boundary on the hydrologic divide to the Ray River drainage at N lat. 66°03.827′ W long. 150°49.988′ at the 2,920 ft. peak of that divide.

(B) Unit 24B consists of the Koyukuk River Drainage upstream from Dog Island to the Subunit 24A boundary.

(C) Unit 24C consists of the Hogatza River Drainage, the Koyukuk River Drainage upstream from Batza River on the north side of the Koyukuk River and upstream from and including the Indian River Drainage on the south side of the Koyukuk River to the Subunit 24B boundary.

(D) Unit 24D consists of the remainder of Unit 24.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public land:

(A) You may not use firearms, snowmobiles, licensed highway vehicles, or motorized vehicles, except aircraft and boats, in the Dalton Highway Corridor Management Area, which consists of those portions of Units 20, 24, 25, and 26 extending 5 miles from each side of the Dalton Highway from the Yukon River to milepost 300 of the Dalton Highway, except as follows: Residents living within the Dalton Highway Corridor Management Area may use snowmobiles only for the subsistence taking of wildlife. You may use licensed highway vehicles only on designated roads within the Dalton Highway Corridor Management Area. The residents of Alatna, Allakaket, Anaktuvuk Pass, Bettles, Evansville, and Stevens Village, and residents living within the Corridor may use firearms within the Corridor only for subsistence taking of wildlife.

(B) You may not use aircraft for hunting moose, including transportation of any moose hunter or moose part in the Kanuti Controlled Use Area, which consists of that portion of Unit 24 bounded by a line from the Bettles Field VOR to the east side of Fish Creek Lake, to Old Dummy Lake, to the south end of Lake Todatonten (including all waters of these lakes), to the northernmost headwaters of Siruk Creek, to the highest peak of Double Point Mountain, then back to the Bettles Field VOR; however, this does not apply to transportation of a moose hunter or moose part by aircraft between publicly owned airports in the controlled use area or between a publicly owned airport within the area and points outside the area.

(C) You may not use aircraft for hunting moose, including transportation of any moose hunter or moose part in the Koyukuk Controlled Use Area, which consists of those portions of Units 21 and 24 bounded by a line from the north bank of the Yukon River at Koyukuk at 64°52.58′ N lat., 157°43.10′ W long., then northerly to the confluences of the Honhosa and Kateel Rivers at 65°28.42′ N lat., 157°44.89′ W long., then northeasterly to the confluences of Billy Hawk Creek and the Huslia River (65°57 N lat., 156°41 W long.) at 65°56.66′ N lat., 156°40.81′ W long., then easterly to the confluence of the forks of the Dakli River at 66°02.56′ N lat., 156°12.71′ W long., then easterly to the confluence of McLanes Creek and the Hogatza River at 66°00.31′ N lat., 155°18.57′ W long., then southwesterly to the crest of Hochandochtla Mountain at 65°31.87′ N lat., 154°52.18′ W long., then southwest to the mouth of Cottonwood Creek at 65°13.00′ N lat., 156° 06.43′ W long., then southwest to Bishop Rock (Yistletaw) at 64° 49.35′ N. lat., 157°21.73′ W long., then westerly along the north bank of the Yukon River (including Koyukuk Island) to the point of beginning. However, this does not apply to transportation of a moose hunter or moose part by aircraft between publicly owned airports in the controlled use area or between a publicly owned airport within the area and points outside the area. All hunters on the Koyukuk River passing the ADF&G-operated check station at Ella's Cabin (15 miles upstream from the Yukon on the Koyukuk River) are required to stop and report to ADF&G personnel at the check station.

(iii) You may hunt brown bear by State registration permit in lieu of a resident tag if you have obtained a State registration permit prior to hunting. You may not use aircraft in any manner for brown bear hunting under the authority of a brown bear State registration permit, including transportation of hunters, bears, or parts of bears. However, this prohibition does not apply to transportation of bear hunters or bear parts by regularly scheduled flights to and between communities by carriers that normally provide scheduled service to this area, nor does it apply to transportation of aircraft to or between publicly owned airports.

(iv) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 30; and in the Koyukuk Controlled Use Area, you may also use bait to hunt black bear Sep. 1–25.

(B) Arctic fox, incidentally taken with a trap or snare intended for red fox, may be used for subsistence purposes.

(C) If you are a resident of Units 24A, 24B, or 24C, during the dates of Oct. 15–Apr. 30, you may use an artificial light when taking a black bear, including a sow accompanied by cub(s), at a den site within the portions of Gates of the Arctic National Park and Preserve that are within Units 24A, 24B, or 24C.

TABLE 24 TO PARAGRAPH (n)(24)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear:	
Unit 24B, that portion within Gates of the Arctic National Park—2 bears by State registration permit	Aug. 10–June 30

TABLE 24 TO PARAGRAPH (n)(24)—Continued

Harvest limits	Open season
Unit 24 remainder—1 bear by State registration permit	Aug. 10–June 30
Caribou:	
Unit 24A, that portion south of the south bank of the Kanuti River—1 caribou	Aug. 10–Mar. 31.
Unit 24B, that portion south of the south bank of the Kanuti River, upstream from and including that portion of the Kanuti-Kilolitna River drainage, bounded by the southeast bank of the Kodosin-Nolitna Creek, then downstream along the east bank of the Kanuti-Kilolitna River to its confluence with the Kanuti River—1 caribou.	Aug. 10–Mar. 31.
Units 24A remainder, 24B remainder—5 caribou per day as follows:	
Calves may not be taken.	
Bulls may be harvested	July 1–Oct. 14. Feb. 1–June 30.
Cows may be harvested	July 15–Apr. 30.
Units 24C, 24D—5 caribou per day as follows:	
Calves may not be taken.	
Bulls may be harvested	July 1–Oct. 14. Feb. 1–June 30.
Cows may be harvested	Sep. 1–Mar. 31.
Sheep:	
Units 24A and 24B (Anaktuvuk Pass residents only), that portion within the Gates of the Arctic National Park—community harvest quota of 60 sheep, no more than 10 of which may be ewes, and a daily possession limit of 3 sheep per person, no more than 1 of which may be a ewe.	July 15–Dec. 31.
Units 24A and 24B (excluding Anaktuvuk Pass residents), that portion within the Gates of the Arctic National Park—3 sheep, no more than one of which may be a ewe, by Federal registration permit only, with exception for residents of Alatna and Allakaket who will report by a National Park Service community harvest system.	Aug. 1–Apr. 30.
Unit 24A, except that portion within the Gates of the Arctic National Park—1 ram by Federal registration permit only.	Aug. 20–Sep. 30.
Unit 24, remainder—1 ram with 7/8 curl or larger horn	Aug. 10–Sep. 20.
Moose:	
Unit 24A—1 antlered bull by Federal registration permit	Aug. 25–Oct. 1.
Unit 24B, that portion within the John River Drainage—1 moose by State harvest ticket	Aug. 1–Dec. 14.
	or
1 antlered bull by State registration permit	Dec. 15–Apr. 15.
Unit 24B, remainder—1 antlered bull by State harvest ticket	Aug. 25–Oct. 1.
or	or
1 antlered bull by State registration permit	Dec. 15–Apr. 15.
Federal public lands in the Kanuti Controlled Use Area, as described in Federal regulations, are closed to taking of moose, except by federally qualified subsistence users of Unit 24, Koyukuk, and Galena.	
Units 24C and 24D, that portion within the Koyukuk Controlled Use Area and Koyukuk National Wildlife Refuge—1 bull.	Sep. 1–25.
1 antlerless moose by Federal permit if authorized by announcement by the Koyukuk/Nowitna National Wildlife Refuge Manager and BLM Field Office Manager Central Yukon Field Office. Harvest of cow moose accompanied by calves is prohibited. A harvestable surplus of cows will be determined for a quota..	Mar. 1–5 to be announced.
or	or
1 antlered bull by Federal permit, if there is no Mar. 1–5 season and if authorized by announcement by the Koyukuk/Nowitna National Wildlife Refuge Manager and BLM Field Office Manager Central Yukon Field Office. Harvest of cow moose accompanied by calves is prohibited. Announcement for the March and April seasons and harvest quotas will be made after consultation with the ADF&G Area Biologist and the Chairs of the Western Interior Alaska Subsistence Regional Advisory Council, and the Middle Yukon and Koyukuk River Fish and Game Advisory Committees..	Apr. 10–15 to be announced.
Unit 24C, remainder and Unit 24D, remainder—1 antlered bull. During the Sep. 5–25 season, a State registration permit is required..	Aug. 25–Oct. 1.
Coyote: 10 coyotes	Aug. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 1–Feb. 28.
Wolf: 15 wolves; however, no more than 5 wolves may be taken prior to Nov. 1	Aug. 10–Apr. 30.
Wolverine: 5 wolverine; however, no more than 1 wolverine may be taken prior to Nov. 1	Sep. 1–Mar. 31.
Grouse (Spruce, Ruffed, and Sharp-tailed): 15 per day, 30 in possession	Aug. 10–Apr. 30.
Ptarmigan (Rock and Willow): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver: No limit	Nov. 1–June 10.
Coyote: No limit	Nov. 1–Mar. 31.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 1–Feb. 28.
Lynx:	
Unit 24A—no limit	Nov. 1–Mar 31.
Units 24B, 24C, and 24D—no limit	Nov. 1–Feb. 28.
Marten: No limit	Nov. 1–Feb. 28.
Mink and Weasel: No limit	Nov. 1–Feb. 28.

TABLE 24 TO PARAGRAPH (n)(24)—Continued

Harvest limits	Open season
Muskrat: No limit	Nov. 1–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Nov. 1–Apr. 30.
Wolverine: No limit	Nov. 1–Mar. 31.

(25) *Unit 25.* (i) Unit 25 consists of the Yukon River drainage upstream from but not including the Hamlin Creek drainage, and excluding drainages into the south bank of the Yukon River upstream from the Charley River:

(A) Unit 25A consists of the Hodzana River drainage upstream from the Narrows, the Chandalar River drainage upstream from and including the East Fork drainage, the Christian River drainage upstream from Christian, the Sheenjek River drainage upstream from and including the Thluichohnjik Creek, the Coleen River drainage, and the Old Crow River drainage.

(B) Unit 25B consists of the Little Black River drainage upstream from but not including the Big Creek drainage, the Black River drainage upstream from and including the Salmon Fork drainage, the Porcupine River drainage upstream from the confluence of the Coleen and Porcupine Rivers, and drainages into the north bank of the Yukon River upstream from Circle, including the islands in the Yukon River.

(C) Unit 25C consists of drainages into the south bank of the Yukon River upstream from Circle to the Subunit 20E boundary, the Birch Creek drainage upstream from the Steese Highway bridge (milepost 147), the Preacher Creek drainage upstream from and including the Rock Creek drainage, and the Beaver Creek drainage upstream from and including the Moose Creek drainage.

(D) Unit 25D consists of the remainder of Unit 25.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public land:

(A) You may not use firearms, snowmobiles, licensed highway vehicles or motorized vehicles, except aircraft and boats in the Dalton Highway Corridor Management Area, which consists of those portions of Units 20, 24, 25, and 26 extending 5 miles from each side of the Dalton Highway from the Yukon River to milepost 300 of the Dalton Highway, except as follows: Residents living within the Dalton Highway Corridor Management Area may use snowmobiles only for the subsistence taking of wildlife. You may use licensed highway vehicles only on designated roads within the Dalton Highway Corridor Management Area. The residents of Alatna, Allakaket, Anaktuvuk Pass, Bettles, Evansville, and Stevens Village, and residents living within the Corridor may use firearms within the Corridor only for subsistence taking of wildlife.

(B) The Arctic Village Sheep Management Area consists of that portion of Unit 25A north and west of Arctic Village, which is bounded on the east by the East Fork Chandalar River beginning at the confluence of Red Sheep Creek and proceeding southwesterly downstream past Arctic Village to the confluence with Crow Nest Creek, continuing up Crow Nest Creek, through Portage Lake, to its confluence with the Junjik River; then down the Junjik River past Timber Lake and a larger tributary, to a major, unnamed tributary, northwesterly, for approximately 6 miles where the stream forks into two roughly equal drainages; the boundary follows the easternmost fork, proceeding almost due north to the headwaters and intersects the Continental Divide; the boundary then follows the Continental Divide easterly, through Carter Pass, then easterly and northeasterly approximately 62 miles along the divide to the headwaters of the most northerly tributary of Red Sheep Creek then follows southerly along the divide designating the eastern extreme of the Red Sheep Creek drainage then to the confluence of Red Sheep Creek and the East Fork Chandalar River.

(iii) Unit-specific regulations:

(A) You may use bait to hunt black bear between April 15 and June 30 and between August 1 and September 25; in Unit 25D you may use bait to hunt brown bear between April 15 and June 30 and between August 1 and September 25; you may use bait to hunt wolves on FWS and BLM lands.

(B) You may take caribou and moose from a boat moving under power in Unit 25.

(C) The taking of bull moose outside the seasons provided in this part for food in memorial potlatches and traditional cultural events is authorized in Unit 25D west provided that:

(*1*) The person organizing the religious ceremony or cultural event contacts the Refuge Manager, Yukon Flats National Wildlife Refuge, prior to taking or attempting to take bull moose and provides to the Refuge Manager the name of the decedent, the nature of the ceremony or cultural event, number to be taken, and the general area in which the taking will occur.

(*2*) Each person who takes a bull moose under this section must submit a written report to the Refuge Manager, Yukon Flats National Wildlife Refuge, not more than 15 days after the harvest specifying the harvester's name and address, and the date(s) and location(s) of the taking(s).

(*3*) No permit or harvest ticket is required for taking under this section; however, the harvester must be an Alaska rural resident with customary and traditional use in Unit 25D west.

(*4*) Any moose taken under this provision counts against the annual quota of 60 bulls.

TABLE 25 TO PARAGRAPH (n)(25)

Harvest limits	Open season
Hunting	
Black Bear:	
Units 25A, 25B, and 25C—3 bears or 3 bears by State community harvest permit	July 1–June 30. July 1–June 30.
Unit 25D—5 bears	July 1–June 30.
Brown Bear:	

TABLE 25 TO PARAGRAPH (n)(25)—Continued

Harvest limits	Open season
Units 25A and 25B—1 bear	Aug. 10–June 30.
Unit 25C—1 bear	Sep. 1–May 31.
Unit 25D—2 bears every regulatory year	July 1–June 30.
Caribou:	
Unit 25A—in those portions west of the east bank of the East Fork of the Chandalar River extending from its confluence with the Chandalar River upstream to Guilbeau Pass and north of the south bank of the mainstem of the Chandalar River at its confluence with the East Fork Chandalar River west (and north of the south bank) along the West Fork Chandalar River—10 caribou. However, only bulls may be taken May 16–June 30.	July 1–June 30.
Unit 25C—up to 3 caribou, to be announced, by a joint Federal/State registration permit	Fall season between Aug. 1 and Sep. 30, to be announced. Winter season between Oct. 21 and Mar. 31, to be announced
Unit 25D, that portion of Unit 25D drained by the west fork of the Dall River west of 150°W long.–1 bull	Aug. 10–Sep. 30. Dec. 1–31.
Units 25A remainder, 25B, and Unit 25D, remainder—10 caribou	July 1–Apr. 30.
Sheep:	
Unit 25A, that portion within the Dalton Highway Corridor Management Area	No open season.
Units 25A, Arctic Village Sheep Management Area—2 rams by Federal registration permit only	Aug. 10–Apr. 30.
Federal public lands are closed to the taking of sheep except by rural Alaska residents of Arctic Village, Venetie, Fort Yukon, Kaktovik, and Chalkyitsik hunting under these regulations.	
Unit 25A remainder—3 sheep by Federal registration permit only	Aug. 10–Apr. 30.
Units 25B, 25C, and 25D—1 ram with full-curl horn or larger	Aug. 10–Sep. 20.
Moose:	
Unit 25A, that portion within the Coleen, Firth, and Old Crow River drainages—1 antlered bull	Aug. 25–Sep. 25. Dec. 1–20.
Unit 25A remainder–1 antlered bull	Aug. 25–Sep. 25. Dec. 1–10.
Unit 25B, that portion within Yukon-Charley National Preserve—1 bull	Aug. 20–Oct. 7.
Unit 25B, that portion within the Porcupine River drainage upstream from, but excluding the Coleen River drainage—1 antlered bull.	Aug. 25–Oct. 7. Dec. 1–10.
Unit 25B, that portion, other than Yukon-Charley Rivers National Preserve, draining into the north bank of the Yukon River upstream from and including the Kandik River drainage, including the islands in the Yukon River—1 antlered bull.	Sep. 5–Oct. 7. Dec. 1–15.
Unit 25B remainder—1 antlered bull	Aug. 25–Oct. 7. Dec. 1–15.
Unit 25C—1 antlered bull	Aug. 20–Sep. 30.
Unit 25D (west), that portion lying west of a line extending from the Unit 25D boundary on Preacher Creek, then downstream along Preacher Creek, Birch Creek, and Lower Mouth of Birch Creek to the Yukon River, then downstream along the north bank of the Yukon River (including islands) to the confluence of the Hadweenzic River, then upstream along the west bank of the Hadweenzic River to the confluence of Forty and One-Half Mile Creek, then upstream along Forty and One-Half Mile Creek to Nelson Mountain on the Unit 25D boundary—1 bull by a Federal registration permit. Permits will be available in the following villages: Beaver (25 permits), Birch Creek (10 permits), and Stevens Village (25 permits). Permits for residents of 25D (west) who do not live in one of the three villages will be available by contacting the Yukon Flats National Wildlife Refuge Office in Fairbanks or a local Refuge Information Technician. Moose hunting on public land in Unit 25D (west) is closed at all times except for residents of Unit 25D (west) hunting under these regulations. The moose season will be closed by announcement of the Refuge Manager Yukon Flats NWR when 60 moose have been harvested in the entirety (from Federal and non-Federal lands) of Unit 25D (west).	Aug. 25–Feb. 28.
Unit 25D, remainder—1 antlered moose	Aug. 25–Oct. 1. Dec. 1–20.
Beaver:	
Unit 25A, 25B, and 25D—1 beaver per day; 1 in possession	June 11–Aug. 31.
Unit 25A, 25B, and 25D—no limit	Sep. 1–June 10.
Unit 25C	No open season.
Coyote: 10 coyotes	Aug. 10–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases): 10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1.	Sep. 1–Mar. 15.
Hare (Snowshoe): No limit	July 1–June 30.
Lynx:	
Unit 25C—2 lynx	Dec. 1–Jan. 31.
Unit 25, remainder—2 lynx	Nov. 1–Feb. 28.
Muskrat:	
Units 25B and 25C, that portion within Yukon-Charley Rivers National Preserve—No limit	Nov. 1–June 10.
Unit 25, remainder	No open season.
Wolf:	
Unit 25A—No limit	Aug. 10–Apr. 30.
Unit 25, remainder—10 wolves	Aug. 10–Apr. 30.
Wolverine: 1 wolverine	Sep. 1–Mar. 31.
Grouse (Spruce, Ruffed, and Sharp-tailed):	
Unit 25C—15 per day, 30 in possession	Aug. 10–Mar. 31.
Unit 25, remainder—15 per day, 30 in possession	Aug. 10–Apr. 30.

TABLE 25 TO PARAGRAPH (n)(25)—Continued

Harvest limits	Open season
Ptarmigan (Rock and Willow):	
Unit 25C, those portions within 5 miles of Route 6 (Steese Highway)—20 per day, 40 in possession	Aug. 10–Mar. 31.
Unit 25, remainder—20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Beaver:	
Unit 25C—No limit	Nov. 1–Apr. 15.
Unit 25, remainder—50 beaver	Nov. 1–Apr. 15.
Coyote: No limit	Oct. 1–Apr. 30.
Fox:	
Red fox (including Cross, Black and Silver Phases): No limit	Nov. 1–Feb. 28.
Arctic fox: No limit	Nov. 1–last day of Feb.
Lynx: No limit	Nov. 1–Mar. 31.
Marten: No limit	Nov. 1–Feb. 28.
Mink and Weasel: No limit	Nov. 1–Feb. 28.
Muskrat: No limit	Nov. 1–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Oct. 1–Apr. 30.
Wolverine:	
Unit 25C—No limit	Nov. 1–Mar. 31.
Unit 25, remainder—No limit	Nov. 1–Mar. 31.

(26) *Unit 26*. (i) Unit 26 consists of Arctic Ocean drainages between Cape Lisburne and the Alaska—Canada border, including the Firth River drainage within Alaska:

(A) Unit 26A consists of that portion of Unit 26 lying west of the Itkillik River drainage and west of the east bank of the Colville River between the mouth of the Itkillik River and the Arctic Ocean;

(B) Unit 26B consists of that portion of Unit 26 east of Unit 26A, west of the west bank of the Canning River and west of the west bank of the Marsh Fork of the Canning River; and

(C) Unit 26C consists of the remainder of Unit 26.

(ii) In the following areas, the taking of wildlife for subsistence uses is prohibited or restricted on public land:

(A) You may not use aircraft in any manner for moose hunting, including transportation of moose hunters or parts of moose during the periods July. 1–Sep. 14 and Jan. 1–Mar. 31 in Unit 26A; however, this does not apply to transportation of moose hunters, their gear, or moose parts by aircraft between publicly owned airports.

(B) You may not use firearms, snowmobiles, licensed highway vehicles or motorized vehicles, except aircraft and boats, in the Dalton Highway Corridor Management Area, which consists of those portions of Units 20, 24, 25, and 26 extending 5 miles from each side of the Dalton Highway from the Yukon River to milepost 300 of the Dalton Highway, except as follows: Residents living within the Dalton Highway Corridor Management Area may use snowmobiles only for the subsistence taking of wildlife. You may use licensed highway vehicles only on designated roads within the Dalton Highway Corridor Management Area. The residents of Alatna, Allakaket, Anaktuvuk Pass, Bettles, Evansville, Stevens Village, and residents living within the Corridor may use firearms within the Corridor only for subsistence taking of wildlife.

(iii) You may not use aircraft in any manner for brown bear hunting, including transportation of hunters, bears or parts of bears. However, this does not apply to transportation of bear hunters or bear parts by regularly scheduled flights to and between communities by carriers that normally provide scheduled service to this area, nor does it apply to transportation of aircraft to or between publicly owned airports.

(iv) Unit-specific regulations:

(A) You may take caribou from a boat moving under power in Unit 26.

(B) In addition to other restrictions on method of take found in this section, you may also take swimming caribou with a firearm using rimfire cartridges.

(C) In Kaktovik, a federally qualified subsistence user (recipient) may designate another federally qualified subsistence user to take sheep or musk ox on his or her behalf. The designated hunter must obtain a designated hunter permit and must return a completed harvest report. The designated hunter may hunt for any number of recipients but may have no more than two harvest limits in his/her possession at any one time.

(D) For the DeLong Mountain sheep hunts, a federally qualified subsistence user (recipient) may designate another federally qualified subsistence user to take sheep on his or her behalf. The designated hunter must obtain a designated hunter permit and must return a completed harvest report. The designated hunter may hunt for only one recipient in the course of a season and may have both his and the recipient's harvest limits in his/her possession at the same time.

TABLE 26 TO PARAGRAPH (n)(26)

Harvest limits	Open season
Hunting	
Black Bear: 3 bears	July 1–June 30.
Brown Bear:	
Unit 26A, that portion within Gates of the Arctic National Park—2 bear by State subsistence registration permit.	July 1–June 30.

TABLE 26 TO PARAGRAPH (n)(26)—Continued

Harvest limits	Open season
Unit 26A remainder—1 bear by State subsistence registration permit	July 1–June 30.
Unit 26B—1 bear	Jan. 1–Dec. 31.
Unit 26C—1 bear	Aug. 10–June 30.
Caribou:	
Unit 26A—that portion of the Colville River drainage upstream from the Anaktuvuk River, and drainages of the Chukchi Sea south and west of, and including the Utukok River drainage—5 caribou per day by State registration permit as follows:	
Calves may not be taken.	
Bulls may be harvested	July 1–Oct. 14. Dec. 6–June 30.
Cows may be harvested; however, cows accompanied by calves may not be taken July 16–Oct. 15	July 16–Mar. 15.
Unit 26A remainder—5 caribou per day by State registration permit as follows:	
Calves may not be taken.	
Bulls may be harvested	July 1–Oct. 15. Dec. 6–June 30.
Up to 3 cows per day may be harvested; however, cows accompanied by calves may not be taken July 16–Oct. 15.	July 16–Mar. 15
Unit 26B, that portion south of 69°30′ N lat. and west of the Dalton Highway—5 caribou per day as follows:	
Bulls may be harvested	July 1–Oct. 14. Dec. 10–June 30.
Cows may be harvested	July 1–Apr. 30.
Unit 26B remainder—5 caribou per day as follows:	
Bulls may be harvested	July 1–June 30.
Cows may be harvested	July 1–May 15.
Unit 26C—10 caribou per day	July 1–Apr. 30.
You may not transport more than 5 caribou per regulatory year from Unit 26 except to the community of Anaktuvuk Pass.	
Sheep:	
Units 26A and 26B (Anaktuvuk Pass residents only), that portion within the Gates of the Arctic National Park—community harvest quota of 60 sheep, no more than 10 of which may be ewes and a daily possession limit of 3 sheep per person, no more than 1 of which may be a ewe.	July 15–Dec. 31.
Unit 26A (excluding Anaktuvuk Pass residents), those portions within the Gates of the Arctic National Park—3 sheep.	Aug. 1–Apr. 30.
Unit 26A, that portion west of Howard Pass and the Etivluk River (DeLong Mountains)—1 sheep by Federal registration permit.	Season may be announced.
Unit 26B, that portion within the Dalton Highway Corridor Management Area—1 ram with ⅞ curl or larger horn by Federal registration permit only.	Aug. 10–Sep. 20.
Unit 26A, remainder and 26B, remainder, including the Gates of the Arctic National Preserve—1 ram with ⅞ curl or larger horn.	Aug. 10–Sep. 20.
Unit 26C—3 sheep per regulatory year; the Aug. 10–Sep. 20 season is restricted to 1 ram with ⅞ curl or larger horn. A Federal registration permit is required for the Oct. 1–Apr. 30 season.	Aug. 10–Sep. 20. Oct. 1–Apr. 30.
Moose:	
Unit 26A, that portion of the Colville River drainage upstream from and including the Anaktuvuk River drainage—1 bull.	Aug. 1–Sep. 14.
Unit 26A, that portion of the Colville River drainage upstream from and including the Anaktuvuk River drainage—1 moose; however, you may not take a calf or a cow accompanied by a calf.	Feb. 15–Apr. 15.
Unit 26A, that portion west of the eastern shore of Admiralty Bay where the Alaktak River enters, following the Alaktak River to 155°00′ W longitude excluding the Colville River drainage—1 moose; however, you may not take a calf or a cow accompanied by a calf.	July 1–Sep. 14.
Unit 26A, remainder—1 bull	Aug. 1–Sep. 14.
Unit 26B, excluding the Canning River drainage—1 bull	Sep. 1–14.
Units 26B, remainder and 26C—1 moose by Federal registration permit by residents of Kaktovik only. Federal public lands are closed to the taking of moose except by a Kaktovik resident holding a Federal registration permit and hunting under these regulations.	May be announced.
Musk ox:	
Unit 26A, that portion west of the eastern shore of Admiralty Bay where the Alaktak River enters, following the Alaktak River to 155°00′ W longitude south to the Unit 26A border—1 musk ox by Federal drawing permit.	Aug.1–Mar. 15.
Units 26A remainder and 26B	No open Federal season.
Unit 26C—1 bull by Federal registration permit only. The number of permits that may be issued only to the residents of the village of Kaktovik will not exceed three percent (3%) of the number of musk oxen counted in Unit 26C during a pre-calving census. Public lands are closed to the taking of musk ox, except by rural Alaska residents of the village of Kaktovik hunting under these regulations.	July 15–Mar. 31.
Coyote: 2 coyotes	Sep. 1–Apr. 30.
Fox, Arctic (Blue and White Phase): 2 foxes	Sep. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases):	
Units 26A and 26B—10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1	Sep. 1–Mar. 15.
Unit 26C—10 foxes	Nov. 1–Apr. 15.
Hare (Snowshoe and Tundra): No limit	July 1–June 30.
Lynx: 2 lynx	Nov. 1–Apr. 15.
Wolf: 15 wolves	Aug. 10–Apr. 30.
Wolverine: 5 wolverine	Sep. 1–Mar. 31.

TABLE 26 TO PARAGRAPH (n)(26)—Continued

Harvest limits	Open season
Ptarmigan (Rock and Willow): 20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Coyote: No limit	Nov. 1–Apr. 15.
Fox, Arctic (Blue and White Phase): No limit	Nov. 1–Apr. 15.
Fox, Red (including Cross, Black and Silver Phases): No limit	Nov. 1–Apr. 15.
Lynx: No limit	Nov. 1–Apr. 15.
Marten: No limit	Nov. 1–Apr. 15.
Mink and Weasel: No limit	Nov. 1–Jan. 31.
Muskrat: No limit	Nov. 1–June 10.
Otter: No limit	Nov. 1–Apr. 15.
Wolf: No limit	Nov. 1–Apr. 30.
Wolverine: No limit	Nov. 1–Apr. 15.

■ 5. Amend § __.27 by revising the introductory text of paragraph (e)(11) and paragraphs (e)(11)(iv), (v), and (xvii) to read as follows:

§ __.27 Subsistence taking of fish.

* * * * *

(e) * * *

(11) *Prince William Sound Area.* The Prince William Sound Area includes all waters and drainages of Alaska between the longitude of Cape Fairfield and the longitude of Cape Suckling. The Lower Copper River Area includes that portion of the Copper River, from a boundary one-half mile upstream of the Copper River Highway to a boundary extending one-half mile downstream of the Copper River Highway, from the west bank of the river near highway mile 27 to the east bank of the river near highway mile 38.

* * * * *

(iv) In the Copper River drainage, you may take salmon only in the waters of the Upper Copper River District or in the vicinity of the Native Village of Batzulnetas and in the Lower Copper River Area.

(v) In the Upper Copper River District, you may take salmon only by fish wheels, rod and reel, or dip nets. In the Lower Copper River Area, you may take salmon only by dip nets and rod and reel. All salmon retained from the Lower Copper River Area must be reported to area managers within 48 hours of harvest.

(A) In the Lower Copper River Area, you may not dip net from a boat.

(B) In the Lower Copper River Area, the salmon fishery opens on June 1 and closes on September 30.

* * * * *

(xvii) In the Chugach National Forest portion of the Prince William Sound Area, and the Lower Copper River Area, you must possess a Federal subsistence fishing permit to take salmon, trout, whitefish, grayling, Dolly Varden, or char. Permits are available from the Cordova Ranger District.

(A) Salmon harvest is not allowed in Eyak Lake and its tributaries, the remainder of the Copper River and its tributaries outside of the Lower Copper River Area, and Eyak River upstream from the Copper River Highway Bridge.

(B) You must record on your subsistence permit the number of subsistence fish taken. You must record all harvested fish prior to leaving the fishing site and return the permit by the due date marked on the permit.

(C) You must remove both lobes of the caudal (tail) fin from subsistence-caught salmon before leaving the fishing site.

(D) Excluding the areas described in paragraph (e)(11)(xvii)(A) of this section, you may take salmon by rod and reel, dip net, spear, and gaff year-round.

(E) For a household with 1 person, 15 salmon (other than pink) may be taken, and 5 cutthroat trout, with only 2 over 20 inches, may be taken; no more than 5 Chinook salmon per household; for pink salmon, see the conditions of the permit.

(F) For a household with 2 persons, 30 salmon (other than pink) may be taken, plus an additional 10 salmon for each additional person in a household over 2 persons, and 5 cutthroat trout, with only 2 over 20 inches per each household member with a maximum household limit of 30 cutthroat trout may be taken; no more than 5 Chinook salmon per household; for pink salmon, see the conditions of the permit.

(G) You may take Dolly Varden, Arctic char, whitefish, and grayling with rod and reel and spear year-round and with a gillnet from January 1 to April 1. The maximum incidental gillnet harvest of trout is 10.

(H) You may take cutthroat trout with rod and reel and spear from June 15 to April 14 and with a gillnet from January 1 to April 1.

(I) You may not retain rainbow/steelhead trout for subsistence unless taken incidentally in a subsistence gillnet fishery. Rainbow/steelhead trout must be immediately released from a dip net without harm.

* * * * *

Sue Detwiler

Assistant Regional Director, U.S. Fish and Wildlife Service.

Bridget Darr

Director of Natural Resources, USDA–Forest Service.

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 493

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS–3326–P]

RIN 0938–AT47

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees and clarify the CLIA fee regulations. This proposed rule includes a proposal to provide sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees. We are proposing to incorporate limited/specific laboratory fees, including fees for follow-up surveys, substantiated complaint surveys, and revised certificates. We are also proposing to distribute the administrative overhead costs of test complexity determination for waived tests and test systems with a nominal increase in Certificate of Waiver (CoW) fees. In addition, we are proposing to clarify the methodology used to determine program compliance fees. This proposed rule would ensure the continuing quality and safety of laboratory testing for the public. This proposed rule would also amend histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes. In addition, this proposed rule would amend the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring) to allow for the imposition of such sanctions on CoW laboratories.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 25, 2022.

ADDRESSES: In commenting, please refer to file code CMS–3326–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

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–3326–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3326–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, CMS, (410) 786–3531, and Jessica Wright, CMS, (410) 786–3838, for general information on CLIA fees.

Jeffrey Pleines, CMS, (410) 786–0684, for the budget and financial impact on CLIA fees.

Sarah Bennett or Cindy Flacks, CMS, (410) 786–3531, for personnel issues.

Penny Keller, CMS, (410) 786–3531, or Jelani Sanaa, CMS, (410) 786–1139, for histocompatibility issues.

Sarah Bennett, CMS, (410) 786–3531, for alternative sanctions for CoW laboratories issues.

Nancy Anderson, CDC, (404) 498–2741, for personnel and histocompatibility issues.

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 website as soon as possible after they have been received: *https://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578), which replaced in its entirety section 353 of the Public Health Service Act (PHSA). Section 353(m) of the PHSA requires the Secretary to impose two separate types of fees: ''certificate fees'' and ''additional fees.'' Certificate fees are imposed for the issuance and renewal of certificates and must be sufficient to cover the general costs of administering the CLIA program, including evaluating and monitoring approved proficiency testing (PT) programs and accrediting bodies and implementing and monitoring compliance with program requirements. Additional fees are imposed for inspections of nonaccredited laboratories and for the cost of evaluating accredited laboratories to determine overall if an accreditation organization's standards and inspection process are equivalent to the CLIA program. These evaluations are referred to as validation inspections. The additional fees must be sufficient to cover, among other things, the cost of carrying out such inspections. Certificate and additional fees vary by group or classification of laboratory, based on such considerations as the Secretary determines relevant, which may include the total test volume and scope of the testing being performed by the laboratories, and only a nominal fee may be required for the issuance and renewal of Certificates of Waiver (CoWs).

In January 2018, we published the ''Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988'' (83 FR 1004). As part of the general solicitation for comments related to the CLIA fees, more than a few commenters noted that the CLIA compliance and additional fees have not been updated since 1997 and supported increasing the fees. Some of these commenters suggested that the CLIA fees be reviewed annually and updated as needed to cover the program costs of performing biennial surveys.

Based on stakeholder comments from the Request for Information (RFI), in the December 31, 2018 **Federal Register**, we

issued a notice with comment period (83 FR 67723 through 67728) (hereinafter referred to as the December 31, 2018 notice). The December 31, 2018 notice increased fees for laboratories certified under CLIA. The December 31, 2018 notice increased CLIA fees by 20 percent to help ensure the CLIA program could continue to be self-sustaining, as required by law. The 2018 increase was intended to give CMS time to propose a process through rulemaking to allow for ongoing changes to the CLIA fees. The changes being proposed in this rule would result in a continuous level of funding that would increase as the obligations to the CLIA program increase and keep the program adequately funded over time.

In September 2020, we released new tools to reduce burdensome paperwork and authorization delays for laboratories seeking CLIA certification. Laboratories now have the option to pay CLIA certification fees on the CMS CLIA program website. Online payments are processed overnight, which is substantially faster than hard-copy checks.[1]

This proposed rule would make changes to the methodology for determining the amount of the CLIA fees as described in the February 28, 1992 final rule with comment period (57 FR 7002) (hereinafter referred to as the February 1992 final rule) and codified in 42 CFR part 493, subpart F—General Administration. The fees for the CoW, Certificate for Provider Performed Microscopy (PPM), and the provisional certificate that we refer to as the Certificate of Registration (CoR) were based on the cost of issuing the certificates. The Certificate of Accreditation (CoA) and Certificate of Compliance (CoC) fees were based on the annual test volume and scope of testing that separated the laboratories into schedules or groups of laboratories. Except where described below, we are generally proposing to continue determining these fees in the same manner as in the February 1992 final rule, with the exception of a change in the amount of the CoW fee.

As one such change, we propose to allocate, directly from the CoW fees, the administrative overhead costs of the Food and Drug Administration (FDA) process to categorize clinical laboratory tests as waived as described in the memorandum of understanding (MOU) between CMS and FDA (IA19–23). We believe this is appropriate because the functions of the FDA under the MOU are to provide administrative support to the CLIA program, specifically by categorizing tests as waived.

In addition, we propose implementing certificate fees for the issuance of replacement and revised certificates. We receive numerous requests daily for replacements of lost and misplaced certificates and for revised copies of certificates after demographic, laboratory director, and/or specialty/subspecialty changes. As a result, thousands of replacement and revised certificates have been generated and mailed annually. We believe this additional certificate fee will encourage laboratories to better manage their certificates, provide accurate information when applying for or updating a CLIA certificate, and cover the costs of producing duplicate or revised documents.

The February 1992 final rule also stated at § 493.645(b)(1) that laboratories issued a CoA would be assessed a fee to cover the cost of evaluating the individual laboratories to determine whether an accreditation program's standards and inspection policies are equivalent to the Federal program. The February 1992 final rule explained that there would be a random sample of 5 percent of all accredited laboratories inspected by HHS, and the findings compared to the findings of the Accreditation Organizations (AOs). The February 1992 final rule stated that all accredited laboratories would share the cost of this activity and that the fees would be the same as for inspections by nonaccredited laboratories. We propose new § 493.645(a)(1) to clarify that all accredited laboratories share in the validation inspections cost. Under § 493.645(b)(1), the accredited laboratories currently pay a fee even though HHS inspects only 5 percent of them annually. The fee is 5 percent of what the inspection cost of an equivalent nonaccredited CoC laboratory would pay based on the test volume and scope (that is, the schedule or group) of the laboratories.

In the February 1992 final rule, the inspection fees for laboratories holding a CoC were based on estimates of the length of time required to perform a laboratory survey in the different schedules multiplied by the estimated hourly rate of three different entities that perform surveys. As outlined in the February 1992 final rule, we believe this methodology was a starting point intended to allow the methodology to be adjusted as historical data and experience were gained. The three inspection entities mentioned in the February 1992 final rule were the state agency, contracted surveyors, and Federal surveyors. Of these three entities, an hourly rate was established solely for the state agencies, as any contracted surveyors' salaries are paid by their contractual amount. The Federal surveyors perform their surveys in conjunction with non-survey work plus actual costs for travel to those surveys. Given this diversity of costs, it is not feasible to determine a Federal hourly rate for just the survey activities.

Due to these difficulties, we propose to cease using the hourly rate outlined in current regulations as the basis for determining compliance inspection fees for laboratories holding a CoC and replace it with the methodology proposed in this rule. We propose to keep inspection fees separated by the schedules as previously determined.

The additional fees allowed for in section 353(m) of the PHSA are fees for determining compliance with the CLIA regulations. Some of these fees were previously included in subpart F but were not implemented due to technical limitations. However, a new data system that can implement these requirements is under development, with an expected startup date of October 2022. Therefore, we propose to implement the collection of additional fees as outlined in the February 1992 final rule, to be effective October 2022, as well as the others in this proposed rule, which would be effective 30 days after the publication of the final rule. We believe the collection of these additional fees will help bridge the shortfall between program expenditures and collections as discussed in section I.A.1.b. of this proposed rule.

The February 1992 final rule provisions codified at 42 CFR part 493, subpart F—General Administration was numbered too close together to allow new provisions or the separation of existing provisions, for clarification, to stay in numerical order. Therefore, we propose to redesignate and renumber some provisions so that the flow of this section is easier to follow. For example, we are proposing to redesignate current § 493.645(a) as § 493.649(a) and remove the current regulatory text at § 493.649. In addition, we propose redesignating current § 493.646 as new § 493.655 to maintain thematic order in that § 493.655, which outlines the payment of fees, is better placed after the provisions discussing the different types of fees. Each such change, including this example, is explained in full at its designated provision within section II. of this proposed rule.

Upon the final rule effective date, which would be 30 days following publication, we propose implementing fee increases as described above. We expect the fee increase to be larger than

[1] *https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Index.*

subsequent fee increases and include an across-the-board increase of twenty percent and an inflation factor (CPI–U) of 1.047. We utilized the CPI–U factors promulgated by OMB as part of their economic assumptions for budgetary estimates. To calculate the 4.7 percent compound factor for the two-year increase, we multiplied together factors for each of the two years as follows:

Factor Year 1 (Budgeted Rate for Fiscal Year (FY) 2022) = 1.023

Factor Year 2 (Budgeted Rate for FY2023) = 1.023

The compounded factor = 1.023 × 1.023 = 1.047.

The 20 percent across-the-board (ATB) increase was determined as the amount that, including newly charged fees and inflation, is the difference necessary to fund in total annual projected program obligations and allow for the gradual accumulation of 6 months' worth of obligations as an operating margin at the start of the year. We have calculated that the one-time 20 percent across-the-board increase would generate approximately 12.7 million dollars annually while the inflation factor would generate approximately 3.1 million dollars. The other proposed fees would generate approximately 6.7 million dollars for a total of approximately 22.5 million dollars per year. We believe this would stabilize the CLIA program and allow us to use the inflation factor for future biennial increases. The actual across-the-board percentage may change based on any new information that becomes available or updated assumptions. The revised certificate fee found at proposed § 493.639(a); the replacement certificate fee found at proposed § 493.639(b); the follow-up surveys, substantiated complaint surveys, and unsuccessful PT on CoC laboratories found at proposed § 493.643(d)(1) through (4); follow-up surveys on CoA laboratories found at proposed § 493.645(a)(2); and substantiated complaint surveys on CoW, PPM, or CoA laboratories found at proposed § 493.645(b) would be implemented on the effective date of the final rule. However, the collection of the fees is dependent on the new data system being online.

1. CLIA Budget Process

Table 1 provides a summary of projected user fee collections, program obligations, and carryover balances through the end of FY 2025. Start of year carryover balances plus anticipated collections at current rates, net of sequester, equals budgetary resources available for obligation, or spending, in a given fiscal year. This amount, less projected program obligations, equals end-of-year carryover. The continued decrease in the projected end-of-year carryover shows financial obligations for the CLIA program continue to significantly outpace user fee collections at current rates. This proposed rule would create sustainable funding in a few different ways.

TABLE 1: CMS Projections for CLIA Obligations and Fee Collections

	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Available Carryover (SOY)*	$37,971,994	$29,503,205	$14,362,115	($2,493,627)	($21,103,458)
New collections	$69,874,000	$63,000,000	$63,000,000	$63,000,000	$63,000,000
Sequester (5.7%)	($3,982,818)	($3,591,000)	($3,591,000)	($3,591,000)	($3,591,000)
Available Budgetary Resources**	$103,863,176	$88,912,205	$73,771,115	$56,915,373	$38,805,542
Obligations	$74,359,971	$74,550,090	$76,264,742	$78,018,831	$79,813,264
Carryover (EOY)*	$29,503,205	$14,362,115	($2,493,627)	($21,103,458)	($41,507,722)

* SOY = Start of Year, EOY = End of Year

** Budgetary resources mean amounts available to be obligated. In this instance it means the sum of available carryover + new user fee collections less projected sequestration.

a. Two-Part Periodic Increase

First, establishing a two-part periodic increase could be easily implemented and would provide an understandable calculation of fee increases. CMS will publish future fee increases in a notice in the **Federal Register**. CMS will not publish a notice in the **Federal Register** if no fee increases are required. Every 2 years, in preparation for the biennial fee increase, we would calculate the inflation adjustment using the Consumer Price Index for all Urban Consumers (CPI–U). At that time, CMS would look back over the previous 2 years and determine if the calculated CPI–U inflation adjustment would be sufficient to cover actual program obligations. If the total fee amounts, including any increase applied, do not match or exceed actual program obligations based on a review of the obligations of the previous 2 years, CMS will apply an additional across-the-board increase to each laboratory's fees by calculating the difference between the total fee amounts and actual program obligations. If CMS determines that the inflation adjustment is not enough to cover the program obligations, an additional across-the-board amount would be added to the adjustment to ensure that the fee increase is spread equally across all fees in a flat percentage amount, which would cover CLIA obligations. The adjusted fees would become part of the baseline for the next biennial increase. If the level of collections was found to be sufficient to cover program obligations, CMS would not implement a biennial inflation adjustment or an across-the-board fee increase. With any fee increase, the amount of the increase and a summary of CLIA obligations along with the calculations of the increase using the CPI–U and any determined shortfall would be published in a notice in the **Federal Register**.

Table 2 shows a representation of the change in national average laboratory fees if the two-part increase was 4 percent over the current fees.

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TABLE 2: Examples, Two-part Increase per Certificate Type *

National Average CoC compliance fee/CoA Validation Survey fee					CLIA Biennial Certificate fees					
Laboratory classification (schedule)	Current average		Example, Biennial Increase of 4%		Current average			Example, Biennial Increase of 4%		
Certificate of Compliance (CoC) & Certificate of Accreditation (CoA)	CoC	CoA	CoC	CoA	CoC/CoA	CoW	PPM	CoC/CoA	CoW	PPM
LVA**	$360	$18	$374.40	$18.72	$180	-	-	$187.20	-	-
A	$1,192	$60	$1,239.68	$62.40	$180	-	-	$187.20	-	-
B	$1,591	$80	$1,654.64	$83.20	$180	-	-	$187.20	-	-
C	$1,988	$99	$2,067.52	$102.96	$516	-	-	$536.64	-	-
D	$2,336	$117	$2,429.44	$121.68	$528	-	-	$549.12	-	-
E	$2,684	$134	$2,791.36	$139.36	$780	-	-	$811.20	-	-
F	$3,032	$152	$3,153.28	$158.08	$1,320	-	-	$1,372.80	-	-
G	$3,380	$169	$3,515.20	$175.76	$1,860	-	-	$1,934.40	-	-
H	$3,728	$186	$3,877.12	$193.44	$2,448	-	-	$2,545.92	-	-
I	$4,076	$204	$4,239.04	$212.16	$7,464	-	-	$7,762.56	-	-
J	$4,408	$220	$4,584.32	$228.80	$9,528	-	-	$9,909.12	-	-
Not applicable	-	-	-	-	-	$180	$240	-	$187.20	$249.60

*Note: The Certificate of Registration (CoR) fee would increase from the $100 to $104.
**LVA "Schedule A, Low Volume".

b. Collection of Other Authorized Fees

The CLIA regulations also authorize the collection of other fees; however, the program has historically not exercised its authority in collecting these fees due to technical difficulties. CMS believes this has been a missed opportunity. With the improvement in technology since 1992, we will be enforcing existing regulatory authority in the collection of these fees as well as clarifying circumstances when such fees are applicable. If finalized, this proposed rule would implement collection of these other fees, which are laboratory specific and provide an incentive for laboratories to remain compliant with all provisions of the CLIA regulations.

The fees include:

- A fee for follow-up surveys to determine correction of the deficient practices found in either a CoC survey or a CoA validation survey;
- An addition of a specialties survey fee when it is necessary to determine compliance of testing in one or more additional specialties outside of the CoC survey cycle;
- A substantiated complaint survey fee;
- A fee for a desk review of unsuccessful PT performance;
- A fee for a replacement certificate when a laboratory loses or destroys a CLIA certificate and requests a replacement certificate; and
- A fee for issuing a revised certificate when the laboratory changes the laboratory director or other information found on a certificate and requests a new certificate to reflect the changes.

Table 3 represents a national average per incident of the amount that would have been collected had these fees been implemented in FY2019. We totaled the number of follow-up surveys, substantiated complaints, and unsuccessful PT events and multiplied them by the national average number of hours recorded by the state survey agencies for these activities and then multiplied that by the national average unit cost, which was $72.06 in 2019. The amounts for the revised certificates and replacement certificates are the fee amount as discussed in section II.C. of this proposed rule, specifically at § 493.639(a).

TABLE 3: Projection of other Authorized Fees per Certificate Type

Projected National Average Other Authorized fees					
Certificate type	**Follow-up surveys (including those for the addition of specialties)**	**Substantiated Complaint Surveys**	**Unsuccessful Proficiency Testing (PT) event**	**Replacement Certificates**	**Revised Certificates**
Certificate of Compliance (CoC)	$329	$1,879	$517	$75	$150
Certificate of Accreditation (CoA)	$329	$5,011	$517	$75	$95
Certificate of Registration (CoR)	$329	$2,802	$517	$75	$150
Certificate of Waiver (CoW)	n/a	$1,364	n/a	$75	$95
Certificate of Provider Performed Microscopy (PPM)	n/a	$2,556	n/a	$75	$150

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2. CoW Fee Increase

This proposed rule would authorize a fee increase for the CoW. A CoW laboratory is limited to performing tests categorized by FDA as waived, which are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or the Secretary has determined pose no unreasonable risk of harm to the patient even if performed incorrectly. Some examples of waived tests include tests for blood glucose or cholesterol. As part of our financial obligations to administer the CLIA program, we compensate FDA for its role in determining if tests and test systems meet criteria to be categorized as waived tests/test systems. This proposed rule would implement a nominal increase for CoW fees which would offset program obligations to FDA for its role under the CMS–FDA MOU (IA19–23) in categorizing tests and test systems as waived. The obligation to CLIA, defined by the MOU and calculated against the number of CoW laboratories, is approximately $25 per laboratory to cover the FDA obligation. The additional $25.00 would increase the current $180.00 biennial CoW fee to $205.00. Due to the public health emergency for COVID–19 and the number of smaller laboratories that hold a Certificate of Waiver, we are proposing to delay the implementation of the one-time $25 fee increase until the Secretary terminates the declaration or allows it to expire.

B. CLIA Requirements for Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories

CLIA requires any laboratory that examines human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health, of human beings to be certified by the Secretary for the categories of examinations or procedures performed by the laboratory. The implementing regulations at 42 CFR part 493 specify the conditions and standards that must be met to achieve and maintain CLIA certification. These conditions and standards strengthen Federal oversight of clinical laboratories and help ensure the accuracy and reliability of patient test results.

CMS is always looking for ways to improve our programs and better serve

our beneficiaries. Concerning laboratory oversight, HHS endeavors to improve consistency in the application of laboratory standards, coordination, collaboration, and communication in both routine and emergent situations, thereby further improving laboratory oversight and, ultimately, patient care. The regulations related to CLIA histocompatibility and personnel requirements have not been updated since 1992 [2] and 2003,[3] and the regulations for CoW laboratory alternative sanctions have not been updated since 1992.[4] HHS believes it is time to update these regulations to reflect the current state of the American health care system and new advances in technology.

HHS sought expert advice to inform our decision-making on the regulatory updates proposed in this rule. We solicited advice on several topics addressed in this rule from the Clinical Laboratory Improvement Advisory Committee (CLIAC), the official Federal advisory committee charged with advising HHS regarding appropriate regulatory standards for ensuring accuracy, reliability, and timeliness of laboratory testing. On January 9, 2018, we also issued a Request for Information [5] (RFI) that solicited input from the public on issues related to CLIA personnel and histocompatibility requirements, and alternative sanctions for CoW laboratories. We received approximately 8,700 total comments in response to the 2018 RFI. The CLIAC recommendations and information received in response to the 2018 RFI helped us determine the policies proposed in this proposed rule.

This proposed rule would amend histocompatibility and personnel regulations to address obsolete regulations and update the regulations to incorporate changes in technology. This proposed rule would also amend § 493.1804(c) to allow alternative sanctions to be imposed on CoW laboratories.

1. Histocompatibility

The CLIA regulations include requirements specific to certain laboratory specialties such as microbiology and subspecialties such as endocrinology. Histocompatibility is a type of laboratory testing performed on the tissue of different individuals to determine if one person can accept cells, tissue, or organs from another person. The CLIA regulatory requirements for the specialty of histocompatibility at § 493.1278, including the crossmatching requirements, address laboratory testing associated with organ transplantation and transfusion and testing on prospective donors and recipients. As of October 2019, 218 CLIA-certified laboratories perform testing in this specialty. The current specialty regulations were published in the 1992 final rule with comment period, and additional changes were made in the 2003 final rule. Specifically, the 2003 final rule changed the regulations to decrease the number of specialty/subspecialty-specific quality control (QC) regulations in instances where general QC requirements would apply. The specialty of histocompatibility has not yet been similarly updated. Many of the changes proposed in this rule would remove histocompatibility-specific requirements from § 493.1278 that we have determined are addressed by the general QC requirements at §§ 493.1230 through 493.1256 and 493.1281 through 493.1299. We believe that removing specific requirements for obsolete methods and practices and eliminating redundant requirements will decrease the burden on laboratories performing histocompatibility testing. We have heard from our stakeholders, particularly the transplantation community, that physical crossmatches are a barrier to modernized decision-making approaches on organ acceptability based on risk assessment.

For the crossmatching regulations that this proposed rule would amend, HHS requested input from CLIAC on the acceptability and application of newer crossmatching techniques in lieu of physical crossmatching. The CLIAC gathered information on the acceptability and application of newer crossmatching techniques for transplantation because there have been advances in the field of transplantation since 1992. These advances have made the physical crossmatch less significant in non-sensitized patients. The CLIAC stated that histocompatibility testing has evolved from cell-based assays to molecular typing and solid-phase platforms for antibody detection, improving accuracy and sensitivity. Significant changes have occurred in the clinical practice of transplantation (immunosuppression, desensitization practices), and improvements in anti-rejection therapies have led to improved outcomes and mitigation of risk due to human leukocyte antigen (HLA) antibodies. At its November 2014 meeting, CLIAC made the following recommendations [6] for CMS to explore:

- Regulatory changes or guidance(s) that would allow virtual crossmatching to replace physical crossmatching as a pre-requisite for organ transplant.
- Appropriate criteria and decision algorithms, based on CLIAC deliberation of the Virtual Crossmatch Workgroup input, under which virtual crossmatching would be an appropriate substitute for physical crossmatching. The determination of appropriate criteria and decision algorithms should involve a process that includes an open comment period.

In the 2018 RFI (83 FR 1005 through 1006, 1008), we requested comments and information related to histocompatibility and crossmatching requirements that may have become outdated and requested suggestions for updating these requirements to align with current laboratory practice. The comments we received in response to the 2018 RFI recommended updating the current histocompatibility and crossmatching requirements to align with current laboratory practices. Both the CLIAC recommendations and the comments on the 2018 RFI informed the changes proposed in this rule.

2. Personnel

The CLIA regulations related to personnel requirements were updated with minor changes to the doctoral high complexity laboratory director (LD) qualifications in the 2003 final rule (68 FR 3713) but otherwise have remained unchanged since we published the 1992 final rule with comment period (57 FR 7002). In the 2018 RFI (83 FR 1005 through 1006, 1008), we sought public comment and information related to CLIA personnel requirements in the following areas: nursing degrees; physical science degrees; personnel competency assessment (CA); personnel training and experience; and non-traditional degrees. As we explained in the 2018 RFI, these are areas that the CDC, CMS, stakeholders, and state agency surveyors identified as relevant to our efforts to update the CLIA

[2] See the ''Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA)'' final rule with comment period (57 FR 7002) that published in the February 28, 1992 **Federal Register** (hereinafter referred to as the ''1992 final rule with comment period'').

[3] See the ''Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications'' final rule (68 FR 3640) that published in the January 24, 2003 **Federal Register** (hereinafter referred to as the ''2003 final rule'').

[4] See the 1992 final rule with comment period.

[5] See the ''Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)'' RFI (83 FR 1004) that published in the January 9, 2018 **Federal Register** (hereinafter referred to as the ''2018 RFI'').

[6] *https://www.cdc.gov/cliac/docs/summary/cliac1114_summary.pdf.*

personnel requirements to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing.

We received approximately 8,700 comments in response to the 2018 RFI. In response to our questions about nursing degrees, the majority of commenters did not concur that nursing degrees were equivalent to a biological or chemical sciences degree. However, some stakeholders suggested nursing degrees could be used as a separate qualifying degree for nonwaived testing personnel (TP). In response to our questions about physical science degrees as well as non-traditional degrees, stakeholders commented that a physical science degree was hard to define. In considering how to evaluate physical science and other non-traditional degrees, some commenters recommended that we evaluate coursework taken using a semester-hour educational algorithm to qualify individuals for CLIA personnel positions. If an individual has the appropriate coursework without the traditional chemical or biological degree, the individual's educational coursework should be considered when determining whether that individual meets the educational requirements under CLIA. In response to the questions about CA, many commenters stated that individuals with an applicable associate's degree should be permitted to perform CA on moderate complexity TP. Some commenters stated that required training should depend on the complexity of the testing to be performed and that all nonwaived testing should require training related to the individual's laboratory responsibilities. Several commenters also stated that any required training and experience should be in a CLIA-certified laboratory. Many commenters agreed that all training and experience should be documented; many noted that documentation from a former employer should be acceptable, assuming it provided specific details about the individual's job, training, and CA.

In addition to the 2018 RFI, we requested input from CLIAC for recommended changes to the CLIA personnel requirements found in subpart M—Personnel for Nonwaived Testing, §§ 493.1351 through 493.1495. In response, CLIAC established a workgroup that included laboratory experts, representatives from accreditation organizations (AOs), and government. The CLIAC Personnel Regulations Workgroup provided information and data to CLIAC for their deliberation in recommending to HHS to updating the personnel regulations.[7] CLIAC made 12 recommendations at the April 2019 meeting to improve CLIA personnel regulations, including: (1) making biological science degrees acceptable for laboratory personnel and considering candidates with other degree backgrounds based on coursework; (2) removing the degree in physical science from the CLIA regulations due to its broadness; and (3) requiring personnel to have training and experience in their areas of responsibility.

After the April 2019 CLIAC meeting, CMS and the Centers for Disease Control and Prevention (CDC) met to review and consider the recommendations along with the information provided in response to the 2018 RFI. The following CLIAC recommendations support proposals included in this proposed rule:

- Coursework should be considered in meeting CLIA personnel requirements;
- Degree in physical science should be removed from CLIA regulations;
- All personnel should have appropriate training and experience;
- Remove the statement ''possess qualification that are equivalent to those required for such certification'', as applicable;
- Laboratory experience should be clinical in nature;
- 20 credit hours should be required for all LDs except those certified by the American Board of Pathology, American Board of Osteopathic Pathology, and American Board of Dermatology;
- Laboratory directors should make at least two reasonably spaced onsite visits to the laboratories they direct annually. These visits should be documented;
- Modify CLIA requirements for technical consultants (TC) to include an associate degree and training and experience; and
- Modify the definition of mid-level practitioner to include registered nurse anesthetists and clinical nurse specialists.

Following this, CMS and CDC collaborated to develop a list of personnel regulation updates proposed in this rule.

3. Alternative Sanctions for CoW Laboratories

In section III.C. of this proposed rule, we are proposing to amend § 493.1804(c)(1) to allow CMS to impose alternative sanctions on CoW laboratories, as appropriate. CoW laboratories are laboratories that only perform waived tests, that is, simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. For example, a urine dipstick pregnancy test is a waived test. The current regulations state that we do not impose alternative sanctions on CoW laboratories because those laboratories are not inspected for compliance with condition-level requirements (§ 493.1804(c)(1)). However, while not subject to the biennial routine surveys, CoW laboratories are surveyed as a result of a complaint, and based on the complaint survey, may be found to be out of compliance with a condition-level requirement. In the absence of alternative sanctions, our only recourse in cases of compliance issues found at CoW laboratories is to apply principal sanctions (that is, revocation, suspension, or limitation of the CLIA certificate). We believe the ability to levy alternative sanctions (that is, civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring) on CoW laboratories helps CMS ensure appropriate sanctions are applied to CoW laboratories, as in the case of other certificate types (certificate of PPM, CoR, CoC, CoA).

In addition, we believe that this proposed change, if finalized, would reduce burden on CoW laboratories. The ability to impose alternative sanctions would be particularly useful in instances in which we find PT referral violations. PT is the testing of unknown samples sent to a laboratory by an HHS-approved PT program to check the laboratory's ability to determine the correct testing results. This proposed rule would amend the CoW regulations at § 493.1804(c)(1) to allow for the application of alternative sanctions where warranted, in addition to or in lieu of principal sanctions.

We note that while the regulatory text at § 493.1804(c)(1) currently specifies that CMS will not impose alternative sanctions on laboratories that have CoWs because those laboratories are not inspected for compliance with condition-level requirements aligns with the statute, this distinction is not required by the applicable statute at 42 U.S.C. 263a(h). Therefore, in section III.C. of this proposed rule, we are proposing to remove the parenthetical ''(CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)'' from § 483.1804(c).

In responses received from the 2018 RFI, commenters noted that alternative

[7] *https://www.cdc.gov/cliac/docs/summary/cliac0419_summary.pdf.*

sanctions instead of principal sanctions should be an option to create parity for all certificate types, especially in cases of PT referral. Further, commenters also stated that CoW laboratories should be held to the same standards and level of compliance as those that perform moderate complexity and/or high complexity testing.

II. Provisions of the Proposed Regulations for CLIA Fees

This section provides an overview of the proposed revisions to the CLIA fee requirements established by the February 1992 final rule.

A. Proposed Definitions of ''Replacement Certificate'' and ''Revised Certificate'' (§ 493.2)

At § 493.2, we are proposing to add definitions for ''Replacement certificates'' and ''Revised certificates.'' After several years of experience and data analysis, it has been determined that the number of reissued certificates continues to be remarkable. Reissued certificates fall into two different categories: revised and replacement certificates. For further discussion please refer to section II.C. of this proposed rule. We are proposing that these definitions be added to § 493.2 with the other definitions listed to allow clarity in the regulations where fees for replacement and revised certificates are being proposed.

B. Proposed Changes to Certificate Fees (§ 493.638)

At § 493.638(a), we are proposing to amend the regulatory language to clarify when a laboratory is required to pay a certificate fee and when the certificate is issued. We removed the listing of the individual certificates in the first paragraph of this section as all certificates go through the same process. The current regulation text specifies when a certificate fee is required, but we wish to clarify with more specific wording. The certificate fee is currently incurred when the original certificate is issued; when the certificate is subsequently renewed; if there is a change in certificate type requiring a new certificate to be issued; or if a lapsed certificate is reactivated with a gap in service and therefore reissued. The intent of the regulation is not changing. We believe adding this clarification would improve transparency concerning the requirement to pay certificate fees.

Specifically, at § 493.638(a)(1) for registration certificates, we are proposing to remove the reference to the CoC because we believe the flat fee charged for a CoR and the temporary nature of the certificate require a separate section. We are proposing to redesignate the fees associated with a CoC to a new provision at § 493.638(a)(5) to keep fee information relevant to the different certificate types separate, rather than referencing the certificate types together.

At § 493.638(a)(2) for CoW, we are proposing to add the costs incurred by FDA to determine whether a test system meets the criteria for waived status, as specified at § 493.15(d). A CMS representative reviews an application for a CoW to determine whether the applicant has requested a CLIA certificate that covers the testing they have listed on the application that they will be performing. The cost of such a review is already part of the CoW fee. However, FDA must expend resources reviewing tests, procedures, and examinations to determine whether a test meets the criteria to be designated as waived. This expense is not currently captured in the fee for a CoW, and we propose that it should be. HHS had delegated the responsibility to FDA for the review of test systems and assignment of complexity, including what is required by § 493.15(d). CMS compensates FDA out of the CLIA funds for this determination under the CMS–FDA MOU (IA19–23). CoW laboratories are restricted to using waived tests. We believe that the regulatory restrictions of test systems for the CoW laboratories and the CMS requirement to determine what tests can be performed in a CoW laboratory under § 493.15(d) require us to place this fee on the CoW laboratories alone. We believe the predicted increase in CoW laboratories will offset expected increases in the obligation to FDA for the continued process of review and categorization of tests as waived.

We are proposing to make editorial changes to clarify the current provision § 493.638(b) that describes certificate fee amounts. We are separating this section into four shorter paragraphs designated as § 493.638(b)(1) through (4). Proposed § 493.638(b)(1) states that CMS will publish a notice in the **Federal Register** when assessed fees are adjusted in accordance with § 493.680. This section also includes a brief discussion of the basis for certificate fees as set forth in § 493.638(c). Proposed § 493.638(b)(2) states that certificate fees would be collected at least biennially. Certificate fees may be assessed more frequently than every 2 years if the laboratory changes its certificate type. Proposed § 493.638(b)(3) states how fees would be determined and proposed § 493.638(b)(4) states that CMS would notify the laboratories when the fees are due and the fee amount. This currently takes place in the form of a fee coupon sent through U.S. Mail by the Billing and Certificate Issuance contractor.

We are also proposing to move the regulatory text currently found at § 493.643(c)(1) through (3) to a new provision at § 493.638(c) to align the provisions more closely for laboratory schedules and specialties with the related provisions concerning certificate fees. Our intent is to refer back to this provision when the compliance fees are discussed. In addition to redesignating this regulatory text, we propose making minor changes to clarify the regulatory text related to specialties of service before those specialties are explained at § 493.643(c)(3).

At the proposed new § 493.638(c)(3), we are proposing to redesignate the regulatory text currently at § 493.643(c)(1) with changes. We believe that the separation of Schedule A into two parts at § 493.643(c)(1)(i)(A) and (B) was confusing, and we propose listing them as separate schedules. The proposed text in the new provision § 493.638(c)(3) now includes § 493.638(c)(3)(i) through (xi). At § 493.638(c)(3)(i), we propose describing the low volume schedule as Schedule V to differentiate it from Schedule A, now proposed at § 493.638(c)(3)(ii). Current data processing system requirements have been built to refer to the low volume A schedule laboratories as Schedule V and will continue with the new data system.

C. Proposed Changes to Fees for Revised and Replacement Certificates (§ 493.639)

At § 493.639, we are proposing to revise the current section heading (''Fee for revised certificate'') to read as ''Fee for revised and replacement certificates'' to match the contents of the section as amended to include both revised certificates and replacement certificates. We are proposing to define and explain revised and replacement certificates in section II.A. of this proposed rule. In this proposed provision at § 493.639 we would further explain the fees associated with each type.

At § 493.639(a), we are proposing to remove the reference to registration certificates as the section applies to all CLIA certificate types under the statutes. We are also proposing to amend the circumstances in which a laboratory may request a revised certificate to include changes to laboratory name and location, laboratory director, or services offered (specialties and subspecialties). We are proposing the fee be based on the national average cost to issue the revised certificate. However, due to differing amounts of

work required per certificate type, the fee is not a single amount. Please see Table 4.

We determined the time and resources required to enter changes to laboratory demographics, review of specialties and subspecialties, and review of laboratory director qualifications using an average of the state survey agencies' calculated unit hourly cost. The state unit hourly cost is determined by the CLIA budget office and is based on a formula of total state costs divided by the total staff years. The total state costs are reported to CMS by the state survey agencies and include staff salaries as determined by each state's civil service pay scale, fringe benefits, travel costs, and other costs such as office supplies, computers containing software required to perform and report a CLIA survey, etc. The total staff year hours are determined by multiplying the number of full-time employees (FTE) by 1600 hours, representing the productive work year.

The time and resources for state agencies to enter demographic changes are less than those where the qualifications of the laboratory director or services need to be reviewed to ensure CLIA personnel requirements are met. Review of laboratory director qualifications applies to laboratories holding a CoC, a certificate of PPM, or CoR.

AOs are responsible for reviewing CoA laboratory director qualifications, and the AO is also responsible for reviewing the addition of specialties and subspecialties for the CoA laboratory. As such, state agency staff are not responsible for reviewing laboratory director qualifications or changes in specialties/subspecialties for laboratories with a CoA; however, they are responsible for processing the other demographic change requests for CoA laboratories. Therefore, a revised certificate for a CoA laboratory does not include the cost to review the qualifications of laboratory directors, nor does it include the adding or deleting of specialties or subspecialties.

For a CoC, a change in services (adding or deleting a specialty or subspecialty) does not include review to determine compliance with the regulations for services added; however, the entry or deletion of specialty or subspecialty changes requires state agency personnel time and resources.

CLIA personnel requirements are not required for laboratories with a CoW, nor are there specialty or subspecialty requirements. Therefore, the time and resources required to enter requested demographic changes for CoW laboratories are less than for other certificate types. Please see the section below for the calculations used to determine these fee amounts.

We are proposing the following fees for issuing revised certificates:

TABLE 4: CMS Proposed Fee for Issuance of Revised Certificate

Certificate Type	Fee
CoW	$95.00
CoA	$95.00
CoR	$150.00
CoC	$150.00
PPM	$150.00

The revised certificate fee would be paid prior to the issuance of the revised certificate. Nonpayment of this fee would not result in the revocation of the laboratory's certificate; however, a revised certificate would not be issued.

At § 493.639(a)(1), we are proposing a new provision explaining that the addition of services (that is, specialties/subspecialties) for laboratories with a CoC may result in an additional fee for purposes of determination of compliance if added services require an inspection. That addition of the specialties inspection fee is described in a new provision at § 493.643(d)(2).

We are proposing to delete the current provisions at § 493.639(b)(1) and (2), which provide information on fees for issuing a revised certificate and scenarios that describe changes that may require a change in certificate. We propose to replace them with a new provision at § 493.639(b) that outlines fees for issuing a replacement certificate. We believe the current provisions are confusing as written and where the provisions are located in the regulations.

At the new provision § 493.639(b), we are proposing a fee for issuance of replacement certificates as discussed in section II.A. of this proposed rule. This proposed requirement must account for the time and resources required to issue a replacement certificate when requested. Historically, replacement certificates have been issued without additional fees when a laboratory loses or destroys its current certificate. We have determined that the actual cost of issuing a replacement certificate is $75.00. A replacement certificate is one where no changes are being requested. The fee would be paid prior to the issuance of the replacement certificate. Nonpayment of this fee would not result in the revocation of the laboratory's certificate; however, a replacement certificate would not be issued.

The calculations used to determine the proposed fee amounts for replacement certificates, and revised certificates were based on the time, and the average state unit costs for 2019 when these fees were set. When these calculations were made, the national average unit hourly cost in 2019 was $72.06. It was determined that it took state agency personnel approximately 45 minutes to receive, review, and enter a request for a replacement certificate and another 15 minutes to print and mail the certificate. The cost of the replacement certificate is calculated to cost the CLIA program $75.00. This cost is rounded up ($72.06 to $75.00) to adjust for the time period needed to finalize the rule.

Furthermore, CMS determined that additional state agency resources are expended when issuing revised certificates as follows:

- An additional 20 minutes to review and enter requested demographic changes or $20.00 for revised CoWs and CoAs.
- An additional 45 minutes to review and enter requested laboratory director changes or specialty changes for $55.00 for revised CoRs and CoCs.

These additional costs are therefore reflected in the proposed fees for issuing revised certificates. (See Table 4)

D. Proposed Changes to Fees Applicable to Laboratories Issued a CoC (§ 493.643)

At § 493.643, we are proposing to rename the section heading ''Fee for

determination of program compliance'' to ''Additional fees applicable to laboratories issued a certificate of compliance'' for clarification.

We are proposing to add language at § 493.643(b) to describe the costs included in the fee for routine inspections to increase transparency. We are proposing to delete the second sentence of § 493.643(b) in consideration of a two-part biennial fee increase as discussed under section II.H. (§ 493.680) of this proposed rule. For clarity, we are proposing to redesignate the third sentence of the current provision at § 493.643(b) as § 493.643(c).

At the new provision § 493.643(c)(1), we are proposing that the inspection fee will be based on the schedules of the laboratories as defined in the new provision under § 493.638(c)(3). The fee amounts assigned to the schedules in the February 1992 final rule were based on an estimated number of hours to perform a survey of a laboratory with the scope and volume associated with each schedule multiplied by an estimated 1992 hourly rate for a surveyor of $35.00. The established hourly rate of $35.00 was intended to be used as a baseline and then revised after actual data were collected and experience gained (57 FR 7193). In 1992 it was anticipated that the universe of regulated laboratories would be much greater than those regulated prior to the implementation of CLIA '88.

The hourly rate for performing laboratory surveys is recalculated by CMS for each state annually to determine the CLIA obligation to support the state survey agencies but has not been used to increase CLIA fees on an ongoing basis. The national average hourly rate in 2019 was $72.06. A description of the national average hourly rate calculation is provided in section II.C. of this proposed rule.

Extensive data collected over time now enables us to better estimate the number of hours it takes for a surveyor to perform an inspection of a laboratory within each schedule. Such estimates are primarily driven by the scope and volume of tests run by the laboratory and the laboratory's compliance with the CLIA regulations. A laboratory with a high-test volume and multiple specialties may have processes and practices that allow it to meet and exceed CLIA regulations as they operate with a high degree of quality and efficiency while ensuring reported results are accurate and timely to provide optimum patient care. The surveyor will likely spend less time on inspecting that laboratory. In contrast, if a laboratory with a small test volume and few specialties does not have processes and practices that allow it to operate with the same high degree of quality and efficiency, such a laboratory is likely not to meet the CLIA requirements. Such laboratories may be reporting test results that may not be accurate and reliable. While the test volume may be low, the surveyor will likely spend additional time surveying such laboratories due to the less-than-optimal operations and processes.

Conversely, the number of hours needed to survey a large laboratory with poor compliance history could be quite large. The surveyor would spend more time in this laboratory, given the size and poor compliance history, the surveyor would review the prior survey deficiencies to ensure the laboratory's monitors put into place have corrected the deficiency. In contrast, a surveyor may not need to spend as many hours to survey a laboratory with lower test volume and specialties but a favorable compliance history. Taking each scenario into account, we believe the average number of hours a surveyor spends in each laboratory reflects the universe of laboratories within each schedule. Thus, we will not be changing the differences between the amounts of the fees within the compliance fee schedules relative to each other. They will remain in their relative amounts and be increased across the board by the same percentage in the proposed two-part fee increase (section II.H. (§ 493.680) of this proposed rule).

Table 5 illustrates the different scenarios mentioned previously in this proposed rule and how the number of hours spent on the survey vary based on both the size (the schedule) of the laboratory and poor compliance with the CLIA regulations. Poor compliance is being defined for this illustration as a laboratory with at least one condition-level deficiency cited during a survey. For information about condition-level deficiencies, please see the CLIA website for the Interpretive Guidelines for Laboratories, Appendix C: Interpretive Guidelines.[8]

[8] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf.*

TABLE 5: Survey Hours with Condition Level Deficiencies Cited vs. Not Cited by Schedule Code

	Condition Level Deficiencies not cited		Condition Level Deficiencies cited	
Schedule code of laboratories that were surveyed*	Number of laboratories**	Range of hours required to perform the individual surveys and the average (avg) number hours**	Number of laboratories**	Range of hours required to perform the individual surveys and the average (avg) number of hours**
V-A	3,446	4 – 69 (avg: 12)	661	5 – 143 (avg: 18)
B-C	1,328	4 – 69 (avg: 13)	320	7 – 123 (avg: 19)
D-E	972	4 – 79 (avg: 15)	261	6 – 201 (avg: 23)
F-G	727	5 - 165 (avg: 18)	192	6 – 378 (avg: 30)
H-I	935	5 – 284 (avg: 21)	279	7 – 497 (avg: 41)
J	110	8 – 213 (avg: 32)	23	8 – 378 (avg: 75)

*For a description of the schedules see the section of this document with the proposed amendments to 42 CFR chapter IV, specifically provision § 493.638(c). The schedules have been grouped as two schedules together to keep the size of the table to a minimum. We are not proposing to change the schedules this way.

**The data comes from the SAS Viya system for surveys completed between 10-01-2017 and 09-30-2019 with condition level deficiencies not cited versus condition level deficiencies cited and separated by schedule codes.

For example, a large laboratory with good compliance in the column titled Condition Level Deficiencies not cited and row J. Additionally, for a medium-sized laboratory (schedules D–E) with no condition level deficiencies cited is 15 hours and ranging to 79 hours. In contrast, the average number of hours spent on survey in small (schedules V–A) laboratories with condition level deficiencies was 18 and ranged to a high of 143 hours. In the largest (schedule J) laboratories, survey hours differed from an average of 32 hours spent in laboratories without condition level deficiencies compared to 75 hours in those laboratories that had condition level deficiencies cited.

The February 1992 final rule did not consider other costs involved in the inspection process, such as continuous training of the state surveyors and monitoring of the state agency program processes by the CMS Locations (Regional Offices). The CLIA program has created and continuously updates periodic training for surveyors through online training modules, onsite meetings, and conference calls.

The surveyors are individually monitored with a Federal Monitoring Survey (FMS) process where CMS location (Regional Office) Federal surveyors observe the individual state surveyor on a survey or perform a survey of the same laboratory after the state surveyor has completed their survey to confirm that the state surveyor is competent and following the prescribed survey process. The CMS locations (Regional Offices) also perform an annual State Agency Performance Review (SAPR) for each state survey agency, including a review of the state survey agency's training processes and monitoring processes for their state surveyors. This includes a review of the deficiency reports state surveyors have sent to laboratories to determine that the surveyor is following the program's principles of documentation and the proper survey process.

There are also costs to the program to maintain a computerized system for entering inspection findings and compliance monitoring, including proficiency testing. The computer system also allows the CMS locations to run reports to monitor the inspections entered by the state surveyors.

The compliance fees have historically been based on the costs to the CLIA program for the State agencies. These aforementioned activities are obligations outside of the state survey agency annual budgets. We are therefore proposing that the determination of inspection fees for laboratories in each schedule and state will no longer be determined solely by the estimated hours spent on a survey of a laboratory within each schedule nor by the surveyor hourly rate of $35.00 established in 1992.

We believe that the compliance fees currently set within the schedules should continue to be used but that additional fees, as previously described, should be added to the regulatory scheme. All fees would be increased biennially following the biennial two-part fee increase as proposed in this rule in § 493.680.

We believe we are authorized to base these fees per laboratory schedule (or group) even though the fees will no longer be determined solely by the estimated hours spent on a survey of a laboratory within each schedule nor by the 1992 surveyor hourly rate of $35.00 based on section 353(m)(3)(C) of the PHSA, which states that, fees shall vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories. We believe our proposals are within the bounds of our authority under the PHSA.

At § 493.643(c)(2), we are proposing to redesignate language from the current § 493.643(b) which states the fees are assessed and payable biennially. We believe this will support the two-part fee increase proposed in this rule and described in § 493.680.

At the new provision § 493.643(c)(3), we are proposing that the fee amount would be the amount applicable to a given laboratory increase listed in the most recent published CLIA fee increase notice in the **Federal Register**.

We are proposing to redesignate current § 493.643(d)(1) and (2) where additional fees for CoC laboratories are discussed at § 493.643(d)(2) and (3) and redesignate the fourth and fifth sentences of current provision § 493.643(b) where an additional fee for a follow-up survey on a CoC laboratory is discussed as a new provision at § 493.643(d)(1). We believe the discussion of additional fees for CoC laboratories should be grouped together.

We are proposing to move the current regulatory text at § 493.643(d)(2) to § 493.643(d)(3) with no changes. Current regulation allows additional fees to be assessed for substantiated complaints; however, this has not been implemented. This proposed rule would

implement fees for substantiated complaints, meaning those complaints where the allegations against the laboratory were found to be true by CMS. We believe implementing the fee for substantiated complaints would cover the costs required to perform such a survey, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and review of the laboratory's plan of correction and monitoring their correction. The fee is proposed to be limited to the cost of the actual time and resources required for these activities.

At new provision § 493.643(d)(4), we are proposing to establish an additional fee for certificates of compliance that are found to have unsuccessful PT through a PT desk review. Current policy requires the review of PT performance every 30–45 days for each laboratory with a CoC that performs testing and is enrolled in PT for an analyte or test included in subpart I. Cases of unsuccessful PT performance require a PT desk review to confirm. Upon confirmation, the laboratory is notified of its regulatory requirement to investigate and correct the unsuccessful PT performance. Currently, such PT desk reviews do not generate an additional fee; however, conducting the desk review requires surveyor time and resources. We believe this new fee would cover the costs of the desk review, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and reviewing the laboratory's plan of correction and monitoring their correction. The fee is proposed to be limited to the cost of the actual time and resources required for these activities. As with the other fees listed in this section, only laboratories with unsuccessful PT performance would be impacted if this rule is finalized. The fees in this section must be paid, or HHS will revoke the laboratory's CoC.

E. Proposed Changes to Additional Fees Applicable to Laboratories Issued a CoA, CoW, or Certificate for PPM Procedures (§ 493.645)

At § 493.645, we are proposing to change the current section heading (''Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures'') to clarify the contents of the section as amended. The proposed title would be ''Additional fees applicable to laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.''

We are proposing to move in its entirety the regulatory text regarding fees for CLIA-exempt laboratory fees by state laboratory programs in § 493.645(a)(1) through (3) to § 493.649(a)(1) through (3). We believe the fees for approved state laboratory programs should be listed separately from the other CLIA-certified laboratories in the regulations. A state laboratory program is a laboratory program that HHS approves as exempt due to the state requirements being equal to or more stringent than the CLIA requirements. Under such programs, the state provides regulatory oversight of its laboratories in lieu of such laboratories regulated by HHS. HHS approves and monitors such state laboratory programs to ensure standards of the state laboratory programs are and remain at least as stringent as the CLIA regulations. HHS does not issue fees to laboratories covered by these programs but charges a fee to the program as described in the new provision at § 493.646.

We are also proposing to make editorial corrections to the references of §§ 493.645(a) and 493.646 noted in §§ 493.557(b)(4) and 493.575(i) and replacing those references with §§ 493.649(a) and 493.655(b). The requirements previously included at §§ 493.645(a) and 493.646(b) governing applicable fees are proposed to be redesignated as § 493.649(a) and new § 493.655(b).

We are further proposing to redesignate current § 493.645(b)(1) and (2) regarding the payment of inspection fees as new § 493.645(a)(1) and (2). We are proposing new § 493.645(a)(1) to clarify the amount accredited laboratories pay for their inspection (validation survey) fees by removing the last sentence of the current regulatory text, which reads that these costs are the same as those that are incurred when inspecting nonaccredited laboratories. We believe this does not fully explain how the fee is determined. This fee is based on fees that CoC laboratories pay for compliance inspections; however, an accredited laboratory is only assessed 5 percent of the fee a CoC laboratory pays because only 5 percent of CoA laboratories are inspected (undergo a validation survey) annually. For example, a CoC laboratory classified as ''schedule D'' pays an average biennial compliance fee of $2,336.00. The accredited laboratory classified as ''schedule D'' would pay an average biennial inspection (validation survey) fee of $117.00.

At new § 493.645(a)(2), we are proposing to redesignate the provision from current § 493.645(b)(2), with no changes. This provision established an additional fee if a laboratory issued a CoA were to be inspected and follow-up visits were necessary because of identified deficiencies. Historically this fee had not been implemented due to technical difficulties described previously in this rule. We are proposing that it be implemented through this proposed rule. As stated in the current regulatory text, the additional fee to cover the cost of these follow-up visits would be based on the actual resources and time necessary to perform the follow-up visits. Also, as stated in the regulatory text, HHS would revoke the laboratory's CoA for failure to pay the fee.

At new § 493.645(b), we are proposing to redesignate the provision from current § 493.645(c). This provision established a fee for substantiated complaint surveys, those in which the allegations against the laboratory were found to be true, on CoA, CoW, or certificate for PPM procedures laboratories. Historically, this fee has not been implemented. We believe implementing the fee for substantiated complaints would cover the costs required to perform such a survey, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and review of the laboratory's plan of correction and monitoring their correction. The fee is limited to the actual time and resources required for these activities.

F. Proposed Changes to Additional Fees Applicable to Approved State Laboratory Programs (§ 493.649)

At § 493.649, we are proposing to delete the current language in its entirety and replace it with language from § 493.645(a)(1) through (3). The current provision at § 493.649 would no longer be needed as the methodology for determining inspection fees in this proposed rule is no longer based on a surveyor hourly rate. At new § 493.649, we are proposing to revise the current section heading (''Methodology for determining fee amount'') to give a clear meaning of the contents of the section as amended. The proposed title is ''Additional fees applicable to approved State laboratory programs.'' We are proposing to replace the current language with current provisions § 493.645(a)(1) through (3) with minor changes (removing ''costs of'' from current 493.469(a)(3)). The provisions at § 493.645(a)(1) through (3) outline the fees applicable to approved state laboratory programs and have been comingled with the provision that outlines the fees for accredited PPM and CoW laboratories. We believe separating

this provision from the other laboratory certificate types will allow for improved readability and understanding.

G. Proposed Changes to Payment of Fees (§§ 493.646 and 493.655)

At § 493.646, we are proposing to redesignate the current provision with minor changes corresponding to the validation survey cost as new § 493.655 and including a reference to § 493.563 that contains the validation inspection information. We believe this provision which outlines the payment of fees, is better placed after discussions of the different types of fees.

We are proposing to redesignate § 493.646(a) and (b) where the payment of fees is discussed to new provisions at § 493.655(a) and (b) with a minor change referencing approved state laboratory programs instead of state-exempt laboratories. The state program pays CMS, not the individual laboratories.

H. Proposed Methodology for Determining the Biennial Fee Increase (§ 493.680)

At new provision § 493.680, we are proposing the biennial two-part fee increase, which would be calculated as described in section I.B. of this proposed rule and published as a notice with a comment period at least biennially. Should the off-year of the biennial increase result in unexpected program obligations, CMS may need to calculate an interim fee increase based on either the CPI–U or difference in obligations and total collected fees or a combination of both. All fees, existing and proposed, mentioned in this proposed rule would also be subject to the biennial two-part fee increase.

III. Provisions of the Proposed Regulations for CLIA Requirements for Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories

This section provides an overview of the proposed revisions to the CLIA requirements for histocompatibility and personnel and application of alternative sanctions for CoW laboratories originally established by the 1992 final rule with comment period (57 FR 7002), subsequently modified in 1995 [9] and 2003,[10] and currently specified in subpart A—General Provisions, subpart K—Quality System for Nonwaived Testing, subpart M—Personnel for Nonwaived Testing, and subpart R—Enforcement Procedures.

A. Proposed Changes to Histocompatibility Requirements

1. General, Human Leukocyte Antigen (HLA) Typing, Disease-Associated Studies, and Antibody Screening and Identification (§ 493.1278(a) Through (d))

At § 493.1278(a)(1), we are proposing to amend the requirement by changing ''an audible alarms system'' to ''a continuous monitoring and alert system'' because this allows the laboratories more flexibility in determining the best way to monitor refrigerator temperatures. It is very important to monitor temperatures continuously, so that recipient and donor specimens and reagents are stored at the appropriate temperature to ensure accurate and reliable testing.

At § 493.1278(a)(2), we are proposing to modify the requirement by expanding the regulatory language to include that the laboratory must establish and follow written policies and procedures for the storage and retention of patient specimens based on the specific type of specimen because the type and duration of specimen storage are equally important as ease of retrieval. We are retaining the requirement that stored specimens must be easily retrievable.

At § 493.1278(a)(3), we are proposing to delete the labeling requirement for in-house prepared typing sera reagent requirement. If a laboratory is performing histocompatibility testing, this requirement under the general reagent labeling requirements for all test systems must be met under § 493.1252(c) and, therefore, is duplicative.

At § 493.1278(a)(4), we are proposing to revise this requirement by removing the examples (that is, antibodies, antibody-coated particles, or complement) to clarify that these technologies, as well as current and future technologies, are allowed for the isolation of lymphocytes or lymphocyte subsets. We are also proposing to clarify the requirement by adding ''identification'' of lymphocytes, or lymphocyte subsets. In this type of testing, lymphocytes can be isolated, but the subsets (B-cells and T-cells) are identified rather than isolated. Due to these proposed changes, § 493.1278(a)(4) would be under the proposed revision at § 493.1278(a)(3).

The current requirement at § 493.1278(a)(5) would be redesignated as § 493.1278(a)(4). This requirement remains unchanged. At § 493.1278(b)(1) through (3), we are proposing to delete these requirements pertaining to establishing HLA typing procedures. The requirement that the laboratory must establish and have written procedures that ensure quality test results are already addressed by the general requirements for all test systems under current § 493.1445(e)(1) and (e)(3)(i) and proposed change at § 493.1278(f), respectively, and therefore, are duplicative.

At § 493.1278(b), we are proposing to redesignate the provisions at paragraph (b)(4) to paragraph (b)(1). At newly redesignated paragraph (b)(1), we are proposing to delete the language that states potential new antigens not yet approved by this committee must have a designation that cannot be confused with WHO terminology because new alleles are approved monthly, which makes this requirement obsolete.

At § 493.1278(b)(5)(i) through (iv), we are proposing to delete the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of HLA antigens as they are already addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.

At § 493.1278(b)(5)(v), we are proposing to modify the requirement to add ''allele'' and delete the ''re'' prefix in the word ''retyping'' in this paragraph. We propose inserting ''allele'' because the regulation only has antigen typing, but there is typing done at the allele level. We are removing redundancy by deleting the ''re'' prefix since CLIA already requires the laboratory to define frequency and criteria for performing typing under the proposed revision at § 493.1278(b)(2).

At § 493.1278(b)(6)(i) through (iii), we are proposing to delete requirements procedures for HLA typing control materials procedures as they are addressed by the general requirements regarding quality control materials and procedures for all test systems under § 493.1256(a) through (d) and (f) through (h), and therefore, are duplicative.

At § 493.1278(c), we are proposing to delete this requirement for control procedures and materials regarding disease related studies because this is addressed by the general requirements for all test systems under §§ 493.1256(d) and 493.1451(b)(4), and therefore, is duplicative.

At § 493.1278(d), we are proposing to change the name of this section from ''Antibody Screening'' to ''Antibody Screening and Identification'' for clarification as both processes apply to histocompatibility testing. The

[9] 60 FR 20047, April 24, 1995 (*https://www.govinfo.gov/content/pkg/FR-1995-04-24/pdf/95-9953.pdf#page=13*).

[10] 68 FR 3640, January 24, 2003 (*https://www.govinfo.gov/content/pkg/FR-2003-01-24/pdf/03-1230.pdf*).

provisions covered under this section apply to both screening and identification. The proposed change at § 493.1278(a)(4) would be under our proposed § 493.1278(c).

At § 493.1278(d)(1) through (3) and (5) through (7), we are proposing to delete these requirements for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.

2. Crossmatching and Transplantation (§ 493.1278(e) and (f))

At § 493.1278(e)(1) through (3), we are proposing to remove these three requirements regarding the laboratory having crossmatch procedures and controls as we believe the provisions to be removed are addressed by the general requirements for all test systems under §§ 493.1445(e)(1), 493.1251, 493.1256, and 493.1451(b)(4), and therefore, are duplicative.

Since 1992, there have been important advances in the field of transplantation and histocompatibility. Based on comments received in response to the 2018 RFI and stakeholder and CLIAC input, we understand the current regulations at § 493.1278 do not reflect the standard practice for laboratories performing testing in the specialty of histocompatibility and are viewed by the transplantation community as a barrier to modernized decision making approaches for organ acceptability. Additionally, we understand that the use of risk assessment and alternative immunologic assessment procedures are currently the standard practice for laboratories performing testing in the specialty of histocompatibility. Therefore, we are proposing to add the requirements summarized below, at § 493.1278(d), to increase flexibility in the regulations and remove perceived barriers. These requirements include:

- Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;
- Defining the criteria necessary to assess a recipient's alloantibody status;
- Assessing recipient antibody presence or absence on an ongoing basis;
- Typing the donor at the serological level, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;
- Describing the circumstances in which a pre- and post-transplant confirmation testing of donor and recipient specimens is required;
- Making available all applicable and donor and recipient test results to transplant team;
- Ensuring immunologic assessments are based on the test report results obtained from a test report from CLIA certified testing laboratory(ies);
- Defining time limits between recipient testing and the performance of crossmatch; and
- Requiring that the test report must specify what type of crossmatch was performed.

At § 493.1278(f), we are proposing to change the words ''transfusion'' and ''transfused'' to ''infusion'' and ''infused'', respectively. The relevance of HLA testing and the decisions of the extent of testing in both a transplant and transfusion setting are critical to both organ and cell acceptance in the host recipient. The use of the word ''transfusion'' is inappropriate given that the product itself is the transfusion but the action of introducing the product is the process of infusion. Transfusion is more specific to immunohematology. There are specific transfusion regulations in the immunohematology section at § 493.1271 that should not be confused with histocompatibility requirements. Since histocompatibility addresses materials that are not always blood products, we believe the term ''infusion'' would be more appropriate. This proposed change at § 493.1278(f) would be under the proposed revision at § 493.1278(e).

At § 493.1278(f)(1), we are proposing to revise this requirement to state that laboratories performing histocompatibility testing must establish and have written policies and procedures specifying the types of histocompatibility testing under the proposed regulation at § 493.1278(e). In addition, we are proposing to add ''identification'' after ''antibody screening'' under our proposed revision at § 493.1278(c), as identification is an important part of the process for crossmatching. Finally, we are proposing to remove ''compatibility testing'' at § 493.1278(f)(1) because this activity is specific to immunohematology, and crossmatching is a more appropriate description of what we understand is the current histocompatibility procedure used by laboratories. The proposed change at § 493.1278(f)(1) would be under our proposed § 493.1278(e).

At § 493.1278(f)(1), we are further proposing to modify the current general requirement to specify that the laboratory must establish and follow written policies and procedures that address the transplant type (organ, tissue, cell) donor type (living, deceased, or paired) and recipient type (high risk vs. non-sensitized). The following terminologies were also updated to reflect current practices: ''cadaver donor'' is replaced by ''deceased donor,'' ''transfused'' is replaced by ''infused,'' and ''combined'' is replaced by ''paired.'' In addition, we believe that clarifying the current regulatory language allows the laboratories to make decisions based on existing technologies and practices for determining what testing is applicable for those transplant programs they serve. The proposed changes at § 493.1278(f)(1) would be under the proposed revision at § 493.1278(e)(1).

At § 493.1278(f)(2) through (3), we are proposing to remove these requirements for renal and nonrenal transplantation crossmatch procedures which are perceived as obstacles to current practices by the transplant community and would allow for alternative immunologic assessment procedures to be used in the designated specialty of histocompatibility. The requirement that the laboratory must establish and follow written policies and procedures test procedures are already addressed in the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1256(c) through (h), and 493.1451(b)(4) and therefore, are duplicative. In addition, we are adding a new requirement for pre-transplant recipient specimens under the proposed § 493.1278(e)(3). Under this new proposed requirement, the laboratory must have written policies and procedures to obtain a recipient specimen for a crossmatch, or to document its efforts to obtain a recipient specimen, collected on the day of transplant. We recognize that the laboratory may not be able to obtain a recipient specimen collected on the day of a transplant since this collection process depends upon the physician obtaining the specimen and submitting it to the laboratory.

At § 493.1278(f)(1)(ii), we are proposing to modify this requirement for laboratory policies and procedures as it would be included in the amended protocol requirements under the proposed regulation at § 493.1278(e)(1)(i) and (iii), and therefore, would be duplicative. The proposed revised requirement reflects current practices in the histocompatibility community.

At § 493.1278(f)(1)(iii), we are proposing to replace ''the level of'' with ''type and frequency'' to clarify this revised requirement refers to the type and frequency of testing practice to support the clinical transplant

protocols. We are also proposing to remove the examples of antigen and allele level in the regulation as these examples may not be all-inclusive and generally are reflected in guidance rather than regulatory text. The proposed change at § 493.1278(f)(1)(iii) would be under our proposed § 493.1278(e)(2).

The requirement at § 493.1278(g) would be redesignated as § 493.1278(f). This requirement remains unchanged.

B. Proposed Changes to Personnel Requirements

CMS recognizes that the COVID–19 public health emergency (PHE) requires flexibility, and we are committed to taking critical steps to ensure America's clinical laboratories can respond during a PHE to provide reliable testing while ensuring patient health and safety. As such, we request that the public provide comments regarding how the CLIA personnel requirements have affected the health system's response to the COVID–19 PHE and any potential opportunities for improvement to such requirements. We welcome suggestions regarding potential improvements that may be specific to a pandemic or public health emergency context, as well as broader recommendations.

1. Definitions (§ 493.2)

a. Midlevel Practitioner

At § 493.2, we are proposing to amend the definition of midlevel practitioner by adding a nurse anesthetist and clinical nurse specialist to the definition. CLIA currently defines a midlevel practitioner as a nurse midwife, nurse practitioner, or physician assistant. We agree with CLIAC's recommendation to include nurse anesthetists and clinical nurse specialists in the definition of midlevel practitioner. We believe including nurse anesthetists and clinical nurse specialists in the definition will be inclusive of current types of mid-level practitioners. For example, the American Association of Nurse Anesthetists (*https://www.aana.com/*) scope of practice states that the practice may include performing point-of-care testing. If the regulations are too specific, some individuals may not qualify when they would have prior to the proposed change.

b. Continuing Education (CE) Credit Hours

At § 493.2, we are also proposing to add a definition for ''Continuing education (CE) credit hours'' to state that it means either continuing medical education (CME) or continuing education (CE) units. Generally, CME refers to continuing education credits earned by physicians (by which we mean doctors of medicine, osteopathy, or podiatric medicine). We propose that CE would be a broader term used for individuals seeking to qualify as laboratory directors who are not physicians. In the current CLIA regulations at § 493.1405(b)(2)(i), CME is considered as acceptable training or experience for individuals to qualify as a LD overseeing moderate complexity testing.

As we are proposing in section III.B. of this proposed rule to require all individuals seeking to qualify as LD for both moderate and high complexity testing to have 20 CE credit hours, we believe we need to establish a more general term for purposes of the proposed requirement. As described below, the CE credit hours would cover all of the LD responsibilities defined in the applicable regulations and must be obtained prior to qualifying as a LD. For example, under proposed § 493.1405(b)(2)(ii)(B), the 20 CE credit hours would be required to cover all of the LD responsibilities defined in § 493.1407 (moderate complexity testing).

The term CME was originally used because it was only required at § 493.1405(b)(2)(i), which is a provision specifically related to doctors of medicine, osteopathy, or podiatry. We believe that including a definition for CE credit hours in the CLIA regulations will respect that historic use, afford a means of referring to a broader range of professionals, and alleviate confusion between the terms.

c. Doctoral Degree

At § 493.2, we are proposing to add a definition for ''doctoral degree'' to state that it means an earned post-baccalaureate degree with at least 3 years of graduate-level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. Originally, degrees were given in medical technology; however, the naming convention for medical technology degrees has changed since the regulations were first published in the 1992 final rule with comment period. The degree is now referred to as clinical laboratory science. A clinical laboratory science degree is synonymous with a medical technology degree. For purposes of 42 CFR part 493, doctoral degrees would not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatry, doctors of veterinary medicine (DVM), or honorary degrees.

We are proposing this modification to CLIA regulations to clarify what we mean by the term ''doctoral degree.'' It seems this general term has created confusion as various stakeholders have asked us the following questions.

- Are doctors of medicine degrees considered to be a type of doctoral degree?
- Does a doctoral degree include traditional (for example, Doctor of Philosophy (Ph.D.), doctorate in science (DSc)) and professional (for example, Doctorate in Clinical Laboratory Science (DCLS)) degrees or does doctoral degree only mean a Ph.D.?

The CLIA regulations for personnel qualifications separate doctors of medicine, osteopathy, and podiatry from other non-medical doctoral degrees by including specific qualification requirements for these three types of degrees. MD and DO degrees pertain to post-graduate level education, specifically in medicine, and are associated with treating illnesses and medical conditions. In contrast, doctoral degrees can be obtained in various fields like biology and chemistry. Historically, we intended a doctoral degree to mean a Ph.D. in a science field related to laboratory work. However, we have come to understand that our doctoral degrees could be interpreted more broadly to include both traditional and professional doctoral degrees. Doctoral degree is a general term used to describe post-graduate level education for various non-medical specific degrees and includes both traditional (for example, Ph.D., DSc) and professional (for example, DCLS) degrees. A traditional earned doctoral degree is generally focused on research and may include academic coursework and professional development. In contrast, a professional earned doctoral degree emphasizes specific skills and knowledge for success in a particular profession without a concentrated focus on research. For example, the DCLS is an advanced professional doctorate designed for practicing clinical laboratory scientists (CLSs) or medical technologists (MTs) who have at least a bachelor's degree and wish to further their level of clinical expertise and develop leadership and management skills. Individuals with a DCLS are experts in clinical laboratory testing. Individuals must have a bachelor's degree in medical technology or clinical laboratory science and the requisite experience in order to be admitted to a DCLS graduate program. The DCLS contributes to increasing laboratory efficiency and improves timely access to accurate and appropriate laboratory information. A graduate of a DCLS

program will be able to: provide appropriate test selection and interpretation of test results; monitor laboratory data and testing processes; improve the quality, efficiency, and safety of the overall diagnostic testing process; and direct laboratory operations to comply with all state and Federal laws and regulations. We would consider a DCLS an acceptable doctoral degree.

For the purposes of qualifying under the CLIA personnel regulations, we do not consider a MD or DO to be the same as a non-medical doctoral degree. Therefore, these individuals must continue to qualify under the applicable CLIA personnel regulations, that is, MDs and DOs must qualify under doctors of medicine or osteopathy requirements. Those individuals with non-medical doctoral degrees as outline above must qualify under the doctoral degree requirements. If finalized, the State Operations Manual (SOM) [11] will be updated accordingly.

The CLIA regulations aim to ensure accurate and reliable testing on specimens derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health of human beings. Therefore, we believe that DVM should be removed from the qualifying doctoral degrees as it is not relevant to testing on specimens derived from the human body. We understand many of the methodologies may be the same; however, testing on human specimens is clearly specified in the statutory language and regulatory definition of a laboratory under CLIA. Therefore, testing of animal specimens does not meet the intent of the CLIA regulations. Of the nine boards approved by HHS for qualification of applicants with doctoral degrees, only one allows individuals with DVMs to sit for board certification. Since 1965, American Board of Medical Microbiology has granted certification to four individuals. Individuals who have previously qualified under a provision requiring a doctoral degree will continue to qualify under the new rule, if finalized. If finalized, we would remove the reference to DVMs in the SOM, Chapter 6 (that is, Interpretive Guidelines) under § 493.1443(b)(3) (page 353).

Finally, as discussed above, we are proposing that a doctoral degree must be an earned post-baccalaureate degree with at least three years of graduate-level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. As such, honorary degrees do not meet the intent of a qualifying doctoral degree as an individual has not completed the necessary course and laboratory work required for the post-baccalaureate degree or necessary to ensure quality testing, for example, accurate and reliable results. We believe that qualifying individuals who hold only honorary degrees is not consistent with the public health purposes of the CLIA statute. Furthermore, we believe that this would impede CMS' ability to ensure health and safety of the public and individuals served by CLIA-certified laboratories.

d. Training and Experience

At § 493.2, we are proposing to add a definition for ''Laboratory training or experience'' to state that it means that the training or experience must be obtained in a facility that meets the definition of a laboratory under § 493.2 and is not excepted from CLIA under § 493.3(b). Laboratory subject to CLIA would mean the laboratory meets the definition of a ''laboratory'' under § 493.2. Training and experience obtained in a research laboratory that only reports aggregate results or a forensic laboratory does not meet this definition. These types of facilities are exempt from CLIA under § 493.3(b), and as such, training and experience acquired in these facilities is not applicable to CLIA laboratories.

In all situations, an individual is required to meet training and/or experience requirements in addition to the educational requirements to competently perform their regulatory responsibilities. Because the CLIA personnel requirements for nonwaived testing are based on the complexity of testing performed (moderate versus high), we conclude that appropriate training and experience is necessary. Comments from the 2018 RFI support this proposal. Comments received from the 2018 RFI include the following:

- Training and or experience should be in a CLIA certified laboratory.
- Research experience is not equivalent to clinical experience.
- Dependent on complexity level of testing, minimum standards should increase as the complexity level increases.

Further, commenters stated that documentation from a former employer would be acceptable, provided it included specific details of the individual's job description, training and CA for areas of testing performed. This documentation could be from an LD, manager or supervisor.

We concur with the CLIAC recommendation that all personnel should have training and experience in their areas of responsibility as listed in CLIA for the appropriate test complexity as shown in Table 6. which shows the specific personnel categories that have a provision requiring training or experience, or both, or require experience directing or supervising, or both.

TABLE 6: Personnel Requirements by Test Complexity for Proposed Personnel Changes that Require Training or Experience, or Both

CLIA Section	Role	Complexity
§ 493.1407(e)	Laboratory director	Moderate
§ 493.1413(b)	Technical consultant	Moderate
§ 493.1425(b)	Testing personnel	Moderate
§ 493.1445(e)	Laboratory director	High
§ 493.1451(b)	Technical supervisor	High
§ 493.1495(b)	Testing personnel	High

[11] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c06pdf.pdf.*

This means personnel should have training or experience examining and performing tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring an individual's condition.

Each individual must have documentation of training or experience applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he or she has the skills required for proper performance of pre-analytic, analytic, and post-analytic phases of testing. For example, if the individual performs blood gas testing on a nonwaived point-of-care device, demonstration of skills should include, but is not limited to, the following:

- Proper specimen collection, handling and labelling;
- Proper test performance according to the laboratory's policies and manufacturer's instructions;
- Verification of performance specifications;
- Calibration and preventive maintenance;
- Proficiency testing; and
- Proper reporting of patient test results.

Training may include, but is not limited to, attendance at:

- Seminars given by experts in the field;
- On-site or off-site instrument trainings given by a manufacturer;
- Technical training sessions, workshops, or conferences given by a professional laboratory organization; or
- A formal laboratory training program.

Documentation may consist of, but is not limited to:

- Letters from training programs or employers.
- Attestation statements of an individual's training and experience by the LD.
- Log sheet(s) initialed by the attendees indicating attendance at a training session or in-service.
- Certificates from organizations providing the training session, workshop, conference, specialty course.

We expect all documentation supporting an individual's education, training and experience to be independently generated, that is, not authored by the individual who is trying to meet CLIA personnel qualification requirements. For example, a curriculum vitae (CV) is not acceptable verification, in and of itself, to document an individual's education, training or experience. Letters on letterhead from previous employment, competency assessment, and comprehensive list of job responsibilities may be examples of acceptable documentation.

Laboratory testing of non-human specimens is not acceptable experience, for example, environmental, animal testing, as it is not used for the purpose of providing information used in the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Many comments received on the 2018 RFI stated that experience from a research laboratory should not be accepted. Depending on the circumstances, research testing can be either exempt from CLIA or subject to CLIA. Specifically, research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients are excepted from the CLIA regulations at § 493.3(b)(2). In accordance with that regulation, only those facilities performing research testing on human specimens that do not report patient-specific results may qualify to be exempt from CLIA certification.[12] An example of a nonpatient-specific result would be ''10 out of 30 participants were positive for gene X.'' The result in this example is a summary of the group data, and is not indicative of an individual's health. An example of a patient- specific result would be ''participant A was positive for gene X'' in which the result is specific to participant A. In cases where patient-specific test results are maintained by a statistical research center for possible use by investigators in which the results are not reported out as patient-specific and could not be used ''for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings,'' CLIA would not apply.

Research testing where patient-specific results are reported from the laboratory, and those results will be or could be used ''for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings'' are subject to CLIA. Therefore, we would consider research experience related to reporting patient-specific results as applicable experience to meet the CLIA personnel requirements; however, if the research experience only includes aggregate reporting of results, we would not consider this acceptable experience to meet CLIA personnel requirements as this type of research testing is exempt from CLIA (§ 493.3(b)(2)).

CLIA regulations at § 493.3(b)(1) specifically exempt facilities or components of facilities that only perform testing for forensic purposes are not subject to CLIA requirements. This was addressed in a Survey and Certification policy memo (S&C–08–35) published on September 5, 2008 (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html*). (*See* the preamble to the 1992 final rule with comment period for an important discussion concerning this subject (57 FR 7014).)

In summary, laboratory results generated purely for the purpose of detecting illegal substances or illegal amounts of certain substances in the body may be relevant to legal proceedings. However, there is no concern in such testing for developing accurate and reliable data for use by health care professionals for the purpose of diagnosis or treatment. The determining factor is not the test itself, but the purpose for which the test is conducted.

In addition, based on the CLIA law and its legislative history, forensic testing is excluded under CLIA since forensic testing is conducted to determine if there has been a violation of the law and is not done for the purpose for providing diagnosis, treatment or assessment of health.

Therefore, we do not consider forensic testing to be acceptable experience or training as a means to meet CLIA personnel requirements as this type of testing is exempt from CLIA (§ 493.3(b)(3)).

e. Experience Directing or Supervising

At § 493.2, we are proposing to add a definition for ''Experience directing or supervising'' to state that it means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under § 493.2 and is not excepted under § 493.3(b). Experience directing or supervising a research laboratory that tests human specimens but does not report patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients would not meet this definition (for example, reporting of aggregate results). Experience directing or supervising any facility or component of a facility that only performs testing for forensic purposes also would not meet this definition. The ordering of tests and interpreting and applying the results of

[12] *https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-and-CLIA.pdf.*

these tests in diagnosing and treating an individual's illness would not meet this definition because it is not related to the performance of clinical laboratory testing. Ordering of tests and interpreting and applying of results falls under the practice of medicine and are not related to the performance of clinical laboratory testing. Teaching experience directly related to a medical technology or clinical laboratory sciences program, or a clinical laboratory section of a residency program, would be considered acceptable experience because we understand that such experience from teaching related to a medical technology or clinical laboratory sciences program would include all aspects of the entire testing process (pre-analytic, analytic and post-analytic), as well as quality control and quality assessment. These are critical responsibilities of a laboratory director as defined by CLIA. See discussion on proposed definition of ''Laboratory training or experience'' for more information on proposed treatment of research laboratories and forensic testing experience.

2. PPM Laboratory Director Responsibilities (§ 493.1359)

At § 493.1359, we are proposing to clarify the CA requirements for PPM laboratories in the Standard for PPM LD responsibilities, as this testing is moderate complexity per § 493.19(b)(2) and subject to CA. Based on the fact the regulations do not have a requirement for a TC for PPM laboratories, we believe that it is currently unclear in the regulation how CA applies to these types of laboratories. The SOM, Appendix C (that is, Interpretive Guidelines) on page 151 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf*) discusses CA for PPM laboratories. Therefore, we are proposing to clarify, via modifications to this LD responsibilities section of the regulations, the CA requirement for PPM laboratories. We are proposing that the competency of all TP would be evaluated to ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. This would include the following:

- Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing;
- Monitoring the recording and reporting of test results;
- Review of test results or worksheets;
- Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and
- Assessment of problem solving skills.

Generally, these requirements mirror the CA provisions for moderate and high complexity testing at §§ 493.1413(b)(8) (TC responsibilities) and 493.1451(b)(8) (TS responsibilities). We are not proposing to include ''Direct observation of performance of instrument maintenance and function checks'' as the only equipment required for PPM testing is limited to bright-field and phase-contrast microscopy. Typically, TP do not perform these activities for PPM testing; rather, they are performed by third-party entities.

In addition, we are proposing at § 493.1359(d) the same CA intervals as in §§ 493.1413(b)(8) and 493.1451(b)(8) apply to mid-level practitioners for consistency. That is, evaluating and documenting the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually.

3. Laboratory Director Qualifications (§ 493.1405)

At §§ 493.1405(b)(1)(ii), 493.1411(b)(1)(ii), 493.1443(b)(1)(ii), and 493.1449, we are proposing to remove ''or possess qualifications that are equivalent to those required for such certification.'' In making this proposal, we acknowledge that there are limited timeframes for an individual to sit for the boards, however, by allowing any such ''eligible'' individual to qualify under our regulations, we have found that some individuals may never sit for exams, or may even fail the exams. Such individuals were not who we intended to be eligible under these provisions. Further, even if we were to ban such individuals by carving them out of those we considered to hold ''qualifications that are equivalent to those required for certification,'' it would be difficult to identify those individuals and remove them from their LD roles. In making this proposal, we acknowledge having historically accepted letters from individuals that have documented proof from the American Board of Pathology or American Board of Osteopathic Pathology that they are eligible to sit for the boards based on SOM guidance (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf,* page 351, D6078). In addition, we propose to eliminate the equivalency standard, as we do not have a means to evaluate equivalency to other boards for equivalency to American Board of Pathology or American Board of Osteopathic Pathology as it would be up to the Board to make a determination of equivalency, and we do not believe in retrospect it would be appropriate to expect those entities to conduct such analyses. Furthermore, we had requested that CLIAC consider what ''possessing qualifications that are equivalent to board certification'' should mean. CLIAC recommended that this verbiage be removed from relevant sections of subpart M because it was confusing, and we have no mechanism to determine when qualifications are ''equivalent to board certification.'' We concur with the CLIAC recommendation. Further, we believe that individuals who historically may have qualified under this provision would still qualify through alternative routes, thus not disadvantaging individuals seeking to qualify as LDs. If finalized, we further propose that an individual who qualified under the predecessor regulations and is currently employed as a LD may continue to serve in that capacity so long as there is no break in service. For example, an individual who is serving as the LD of a CLIA-certified laboratory at the date of the publication of the final rule, and continues to serve as a LD of CLIA-certified laboratory that performs nonwaived testing, would continue to qualify. However, an individual who does not continue as LD of a CLIA-certified laboratory after the date of implementation of the final rule would need to requalify under the new provisions.

At § 493.1405(b)(2)(ii)(A), we are proposing to change the ''or'' to an ''and'' to include directing or supervising nonwaived laboratory testing in the provision. In addition, we are proposing to remove ''Beginning September 1, 1993'' from § 493.1405(b)(2)(ii)(B) and continue to retain the provision for 20 hours of CE credit hours for moderate complexity LDs who are seeking to qualify without certification by the American Board of Pathology and the American Board of Osteopathic Pathology. We believe by requiring the 20 CE credit hours, the LDs would have a better understanding of their responsibilities in the overall management and direction of laboratories, which would result in improved overall compliance. Historically, LD citations are among the top 10 condition-level deficiencies cited by surveyors. We believe that this would also improve the ability of laboratories to report accurate and

reliable test results, thus helping to protect the health and safety of the public.

At §§ 493.1405(b)(2)(ii)(C) and 493.1443(b)(2)(i), we are proposing to remove the residency provision for the following reasons. First, the residency requirement causes confusion with board certification for doctoral degrees (for example, American Board of Internal Medicine). It is also challenging for these individuals to qualify under this provision as the medical residencies as generally do not include the type of laboratory training or require the 1 year of laboratory training that we would expect to see related to laboratory administration and operation for which the LD is responsible. We would expect the residency program to provide the director the knowledge in principles and theories of laboratory practice, including: quality control and quality assessment; proficiency testing; the phases of the total process (that is, pre-analytic, analytic, and post-analytic), as well as general laboratory systems; facility administration; and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing. However, a typical residency does not include performing laboratory training for a year (defined in interpretive guidelines as 2,080 hours of laboratory training) nor does it include knowledge in principles and theories of laboratory practice. We have observed, and AOs have noted to us, that very few individuals qualify through the medical residency route. The onus for providing the documentation related to clinical laboratory experience during residency is on the applicant (that is, it must be documentation of the individual's clinical laboratory experience during residency).

CLIAC recommended that we clarify the residency requirements by emphasizing the requisite laboratory training must be ''clinical laboratory training,'' meaning ''have at least one year of clinical laboratory training during medical residency or fellowship.'' However, we believe that 1 year of laboratory training is vague. We also believe that after removing the residency requirement, there would be several alternative routes for individuals to qualify as LDs. Individuals seeking to qualify as a moderate complexity LD may still qualify under § 493.1405(b)(3) through (5) without a medical residency. We would continue to accept residency experience as counting toward the requirement of 2 years of laboratory experience directing or supervising high complexity testing for doctors of medicine, doctors of osteopathy, or doctors of podiatry. We would also accept experience directing or supervising high complexity testing from a medical fellowship program toward the requirements outlined in the regulations. Generally, a fellowship program follows a residency program and is for those individuals who choose to pursue additional training in their specialty. Section 493.1443(b)(2)(ii) is the current requirement that allows individuals with at least 2 years of experience directing or supervising high complexity testing to qualify under paragraph (b)(2).

At § 493.1405(b)(3), we are proposing to revise paragraph (b)(3)(ii) to include an educational option that includes a qualification algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology (see section I.D.1.a of this proposed rule). We are also proposing to add paragraph (b)(3)(iii) to include the addition of 20 CE credit hours for doctoral degrees, as well as the current paragraphs (b)(3)(i) through (ii). This would include the requirement to be certified by an applicable board and continue to be certified and have at least 1 year of experience directing or supervising nonwaived testing.

The current CLIA regulations at §§ 493.1405, 493.1411, 493.1423, 493.1441, 493.1449, 494.1461, and 493.1489 indicate acceptable degrees for personnel as those in a chemical, physical, biological, or clinical laboratory science or medical technology. Degree names and types have changed since the CLIA regulations were first published in 1992. As a result, in some cases, there are degrees for which the area of study may not be clear based on the name of the degree given. This makes it challenging for CMS, state agencies, Exempt States (ES), and AOs to determine what types of degrees are considered acceptable degrees in order to qualify CLIA personnel. At the time the CLIA regulations were published, individuals typically received a degree in the areas of biology, chemistry, medical technology, or clinical laboratory science. Today, we often must perform an evaluation of transcripts to determine if the individuals meet CLIA personnel requirements.

We believe it is important that individuals lacking a traditional degree in chemical, biological, or clinical laboratory science or medical technology should be considered if they have completed the coursework that is equivalent to the aforementioned traditional degrees and acquired documentation of the equivalent educational coursework. In addition to the educational requirements discussed in this section, CLIA also has experience and training requirements (see our proposed updates to §§ 493.1405, 493.1411, and 493.1423), but they will not be addressed in this educational discussion.

We believe degrees should be in a science that deals in the kind of clinical laboratory testing, that is, that which is related to testing of human specimens as the definition of a ''laboratory,'' which is defined in terms of the examination of materials from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings (see § 493.2). In some cases, it is clear that a degree would meet these standards. For example, degrees in microbiology, genetics, molecular biology, biochemistry, and organic chemistry would be considered appropriate degrees. In other instances, it is not apparent whether the degree would meet such requirements. Environmental sciences, biotechnology, and marine biology are examples of degrees that would not appear in keeping with the scope of the CLIA program. At face value, we do not believe these types of degrees should qualify an individual under the requirements in subpart M because they are not related to clinical laboratory testing. Environmental science degrees may cover such areas as ecosystem management, the impact of industrialization on the environment, and natural resource management. Biotechnology degrees focus on developing technologies and products related to medical, environmental, and industrial areas. Marine biology focuses on studying marine organisms, their behaviors, and interactions with the environment. We would not consider these to be appropriate degrees under the CLIA program because these degrees do not generally appear to be focused on clinical laboratory testing or focused on the testing of human specimens, which is the scope of the CLIA regulations. However, in this proposed rule, we are proposing an option for an educational algorithm based on semester hours as an alternative qualification mechanism. Individuals with degrees that are not clearly biological or chemical in nature may be evaluated using this algorithm if finalized and may qualify for CLIA personnel positions in subpart M.

In developing the proposed algorithm, we explored the required courses for bachelor's, master's, and doctoral degrees in the major studies of biology,

chemistry, and medical technology. For purposes of this discussion, only degrees in biology and chemistry will be addressed, as degrees in medical technology and clinical laboratory science do not need to be evaluated for equivalency. Multiple sections of the CLIA regulations specify that educational degrees in ''chemical, physical or biological science or medical laboratory technology from an accredited institution'' constitute appropriate education to qualify for laboratory roles in the noted complexity and laboratory specialty areas. In all situations, the educational requirement is based on the laboratory individual having a sufficient educational background (coursework) to be qualified to gain the subsequent training and experience to competently perform their roles.

Three levels (small, medium, and large) of both public and private accredited universities and colleges were reviewed. For purposes of this research, small institutions were defined as less than 5,000 students, medium as 5,000 to 15,000 students, and large as greater than 15,000 students. Seven colleges and universities were evaluated for all three defined types. Table 7 describes the number of semester hours (SH) required across all three sizes of colleges and universities for both a bachelor's in Biology and a bachelor's in Chemistry.

TABLE 7: Average Required Semester Hours (SH)* for Bachelor's Degrees in Biology and Chemistry

Semester Hours (SH)	Bachelor's Biology	Bachelor's Chemistry
Biology SH	20-49	≥8**
Chemistry SH	8-20	25-56
Other (Includes biology/chemistry)	7-28	11-42

* Quarter hours may be converted to semester hours by multiplying the semester hours by 1.5. For example, 3 semester hours is equivalent to 4.5 quarter hours.
**The majority of colleges and universities did not break out the biology SH, but instead grouped them in "Other".

In general, accredited colleges and universities require general biology, molecular biology or genetics, general chemistry, organic chemistry, and biochemistry. We are proposing a specific coursework algorithm to qualify candidates, in lieu of a qualifying degree, for all testing levels. At present, only § 493.1489(b)(2)(ii) specifies specific coursework required. This is for an associate degree individual to perform high complexity testing. Specifying coursework requirements will allow CMS, state agencies, AOs, and ES to consistently evaluate educational qualifications.

For both the doctoral degree and master's degree curricula, there were no consistent coursework thesis or research requirements for Biology and Chemistry majors of study. For example, evaluation of the master's degree requirements revealed three tracks that included:

- Coursework;
- Coursework and thesis; and
- Coursework, thesis, and research.

For doctoral degrees, we will propose the following educational algorithm for those individuals who have a doctoral degree that is not clearly in a chemical or biological science. We would expect those individuals to:

- Meet master's degree equivalency; and
- At least 16 SH of additional doctoral-level coursework in biology, chemistry, medical technology, or clinical laboratory science; and
- A thesis or research project in biology, chemistry, medical technology, or clinical laboratory science related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of or the assessment of the health of human beings.

CLIAC recommended that other degrees (such as those in the humanities, physical sciences, and others) may not have the requisite science coursework, and candidates for positions should be considered based on a minimum number of hours of courses with laboratory components with relevance to clinical laboratory testing (which could also come from post-degree curricular work). We concur with CLIAC's recommendation that relevant science and laboratory coursework should be considered when evaluating an individual's education qualifications.

The educational algorithm may allow individuals without a traditional chemical or biological degree to meet the CLIA personnel education requirements based on their coursework. Individuals who may have the appropriate coursework would not be disadvantaged by having a degree that is not considered chemical or biological in nature. Please note that the requirements for the applicable laboratory training or experience, or both, found in subpart M (and discussed previously), are required in addition to the educational requirement.

At § 493.1405(b)(4), we are proposing to redesignate current paragraphs (b)(4)(ii) and (iii) as paragraphs (b)(4)(iv) and (v), respectively. We are proposing new paragraphs (b)(4)(ii) and (iii) as additional educational options that include a qualification algorithm for an individual that does not have a master's degree in a chemical, biological, or clinical laboratory science or medical technology (see section I.D.1.c. of this proposed rule). We are proposing to add a new requirement at paragraph (b)(4)(vi) to include the addition of 20 CE credit hours.

As a result of the above discussion, we are proposing that individuals meet either of the following two options for use as educational algorithms:

- Option 1

++ Meet bachelor's degree equivalency; and

++ At least 16 SH of additional graduate level coursework in biology, chemistry, medical technology, or clinical laboratory science; or

- Option 2

++ Meet bachelor's degree equivalency; and

++ At least 16 SH, which may include a combination of graduate level coursework in biology, chemistry, medical technology, or clinical laboratory science and a thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

At § 493.1405(b)(5), we propose to redesignate current paragraphs (b)(5)(ii) and (iii) to paragraphs (b)(5)(iii) and (iv), respectively. In addition, we are proposing a new paragraph (b)(5)(ii) with an educational option that includes a qualification algorithm for an individual that does not have a bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology (see section I.D.1.c. of this proposed rule). We are also proposing to add a new requirement at paragraph (b)(5)(v) to include the addition of 20 CE credit hours.

In general, an associate degree requires the completion of 60 semesters, and a bachelor's degree requires the completion of 120 semester hours. In the case of bachelor's degrees, for this reason, we are proposing that the equivalent educational requirements for associate degrees at § 493.1489(b)(2)(ii) should be doubled. That is, an individual must have at least 120 SH, or equivalent, from an accredited institution that, at a minimum, include either 48 SH of medical laboratory technology or clinical laboratory science courses; or 48 SH of science courses that include: 12 SH of chemistry, which must include general chemistry and biochemistry or organic chemistry; 12 SH of biology, which must include general biology and molecular biology, cell biology or genetics; and 24 SH of chemistry, biology, or medical laboratory technology or clinical laboratory science in any combination. *Note:* We are not proposing to amend the education SH requirements at § 493.1489(b)(2)(ii) in this proposed rule, as there is no need to amend.

In addition to the degrees discussed above, we are proposing a new framework for evaluating non-traditional degrees, a part of the educational algorithm described previously. One example of a non-traditional degree may be a Regents Bachelor of Arts (RBA), which is a baccalaureate degree program designed for adult students. The basic principle of an RBA is that credit is awarded for what students know regardless of how that knowledge was obtained. In other words, students may earn college-equivalent credit for work and life experiences that can be equated to college courses. It is designed to provide students with a comprehensive general education. Many times, no specific courses are required for graduation, allowing students to design their own programs of study. This degree is usually awarded by a Board of Regents. It is a general education degree without the designation of a major. Many of these individuals have an associate degree in medical laboratory technology (MLT), but not an appropriate bachelor's degree that would make them eligible to qualify under the provisions in CLIA personnel requirements that require minimum of a bachelor's degree. This becomes problematic because there is no designation of a major, and CLIA qualifies individuals with the highest academic degree applicable to CLIA. Generally, in these cases, we have seen that these individuals have an associate degree (AA) degree in MLT and have many years of clinical laboratory experience. Currently, these individuals cannot meet CLIA personnel qualifications in subpart M that require a minimum of a bachelor's degree. We believe that their education and experience should qualify them to be TCs as long as their AA is in medical laboratory technology or laboratory science. Public feedback from the 2018 RFI supported that a non-traditional degree should be considered as a means to meet CLIA requirements for the TC and TP for moderate complexity testing, providing a minimum number of semester hours were obtained in chemistry, biology, and laboratory sciences. We believe a non-traditional degree can be a means to qualify as TC and TP, providing an adequate number of biology, chemistry or medical laboratory, or clinical laboratory science courses is part of the curriculum in addition to meeting the training or experience requirements.

At § 493.1405(b)(6) through (7), we are proposing to remove the ''grandfather'' provisions as these requirements had to have been met by February 28, 1992. Individuals can no longer qualify under these provisions. A grandfather is a provision in which a previous rule would continue to apply to individuals already qualified and employed in the given personnel capacity upon implementing a new rule. The new rule will apply to all individuals seeking to qualify after the implementation of said rule. We propose to revise paragraph (b)(6) with a new grandfather provision for all individuals who qualified under this provision, as well as § 493.1406 prior to the date of the final rule. We intend to allow individuals already qualified and employed in the given personnel capacity as of the date of the final rule to continue to be qualified under the new provisions (that is, grandfathered). However, we intend to require all individuals becoming employed by a laboratory or changing assignments within a laboratory after the final rule's effective date to qualify under the new provisions. This includes those individuals who may have been previously employed in a given position prior to the effective date but took a break or a leave of absence and came back after the date of the final rule.

4. Laboratory Director Qualifications on or Before February 28, 1992 (§ 493.1406)

At § 493.1406, we are proposing to remove the grandfather provision for these requirements as they had to have been met by February 28, 1992. Individuals can no longer qualify under these provisions. We plan to grandfather all individuals qualified under this provision prior to the date of the final rule under § 493.1405(6). All individuals qualifying after the date of the final rule will be required to qualify under the new provisions.

5. Laboratory Director Responsibilities (§ 493.1407)

At §§ 493.1407(c) and 493.1445(c), we are proposing to revise the requirements so that the LD must be on-site at the laboratory at least once every 6 months, with at least a 4-month interval between the two on-site visits. However, laboratory directors may elect to be on-site more frequently. The laboratory must provide documentation of these visits, including evidence of performing activities that are part of the LD responsibilities. We concur with CLIAC's recommendation that LDs should make at least two (reasonably spaced) on-site visits to each laboratory they direct per year. We would expect the on-site visits to be once every 6 months with an interval of at least 4 months between the two on-site visits. We will continue to require that the LD is accessible to the laboratory to provide telephone or electronic consultation as needed. Based on a review of information provided by state agencies, AOs, and ESs, onsite LD on-site visits are required as follows:

- 18 percent (n=9 of 49) of states require on-site visits and one territory;
- 71 percent (n=3 of 7) AOs; and
- 100 percent (n=1 of 2) ES.

CLIA statistics show that LD citations are consistently among the top 10 condition-level deficiencies cited by surveyors.[13] Feedback from the states, AOs, and ES indicated that the number of deficiencies cited at the time of the survey was less when the LD was on-site full-time or made regular on-site visits. Based on anecdotal information from the state agencies, ES, and AOs, the laboratories that did not have a LD who made regular visits to the

[13] *https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf.*

laboratory tended to have an increased number of citations related to overall noncompliance with laboratory requirements. Some states currently require on-site laboratory directors to visit their laboratory at prescribed intervals, while others do not (see Table 8 for a complete list of states and territories). Feedback from states and AOs that did not have such a requirement for on-site visits, generally supported the addition a requirement for on-site visits. Further, on-site visits are meant to supplement regular interactions between off-site directors and the lab (for example, by telephone or other telepresence). We concur with CLIAC's recommendations that clear documentation of LD on-site visits should demonstrate the laboratory is in continuous compliance with current laws and regulations, including but not limited to the assessment of the physical environment for safe laboratory testing. The on-site LD visits cannot be delegated. We believe adding the on-site requirement supports increased compliance for laboratories.

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TABLE 8: State and Territorial Requirements for On-site Laboratory Directors Every 6 Months

Requirement for On-site Laboratory Directors Every 6 Months	Do not Require On-site Laboratory Directors Once Every 6 Months
Georgia	Alabama
Hawaii	Alaska
Maine	American Samoa (territory)
Maryland	Arkansas
Nevada	Arizona
New York	California
Oklahoma	Colorado
Pennsylvania	Connecticut
Rhode Island	Delaware
Tennessee	District of Columbia
Puerto Rico (territory)	Florida
	Guam (territory)
	Idaho
	Illinois
	Indiana
	Iowa
	Kansas
	Kentucky
	Louisiana
	Massachusetts
	Michigan
	Minnesota
	Mississippi
	Missouri
	Montana
	North Carolina
	North Dakota
	Nebraska
	New Hampshire
	New Jersey
	New Mexico
	Ohio
	Oregon
	Saipan (territory)
	South Carolina
	South Dakota
	Texas
	Utah
	Vermont
	Virginia
	Virgin Islands (territory)
	Washington
	West Virginia
	Wisconsin
	Wyoming
N=10 states + 1 US territory	N=40 states,4 US territories, + District of Columbia

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6. Technical Consultant Qualifications (§ 493.1411)

As discussed in section II.B.3. of this proposed rule, we are proposing to amend § 493.1411(b)(1)(ii) by removing ''or possess qualifications that are equivalent to those required for such certification.''

As discussed in section II.B.16. of this proposed rule, we are proposing to amend § 493.1411(b)(3)(i) by removing an earned doctoral, master's, or bachelor's degree in ''physical science'' as a means to qualify. We further propose to redesignate current paragraph (b)(3)(ii) as paragraph (b)(3)(iii). Then, we propose to revise paragraph (b)(3)(i) by changing the ''and'' to an ''or'' and to add a requirement at new paragraph (b)(3)(ii) to meet either § 493.1405(b)(3)(ii) or (b)(4)(ii) or (iii) to allow individuals

who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TC using the educational algorithm.

As discussed in section II.B.16. of this proposed rule, we are proposing to revise § 493.1411(b)(4)(i) by removing a doctoral, master's, or bachelor's degree in ''physical science'' as a means to qualify, and adding an earned doctoral, master's, or bachelor's degree in ''clinical laboratory science'' as a means to qualify. At § 493.1411(b)(4), we are proposing to change the ''and'' to an ''or'' in paragraph (b)(4)(i). We are also proposing to redesignate current paragraph (b)(4)(ii) as paragraph (b)(4)(iii) and to add new paragraph (b)(4)(ii) to state that the individual must meet the criteria in § 493.1405(b)(5)(ii) to allow individuals who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TC using the educational algorithm. We would also redesignate current paragraph (b)(5)(ii) as paragraph (b)(5)(iii) with the addition of ''or.''

At § 493.1411(b), we are proposing to add a requirement at paragraph (b)(5) to allow individuals with an associate degree in medical laboratory technology or clinical laboratory science and at least 4 years of laboratory training or experience, or both, in nonwaived testing and the designated specialty or subspecialty areas of service for which the TC is responsible for qualifying as TCs. As discussed in section I.B. of this proposed rule, CLIAC recommended that we modify CLIA requirements to add the option for individuals with an associate degree to qualify as TCs. We concur with the CLIAC recommendation. In general, this will allow individuals who may have an applicable associate degree in addition to required training or experience, or both, to qualify as TCs. We recognize that the current personnel qualifications for general supervisors (GS) for high complexity testing may be less stringent than those of TCs for moderate complexity testing. The current CLIA regulations allow an individual with an associate degree (§ 493.1461) to perform CA on high complexity TP (see §§ 493.1461(c)(2), 493.1489(b)(2)(i)). The regulations under moderate complexity state that the TC is responsible for CA and does not allow delegation of this responsibility to any individual. The high complexity regulations allow the LD or TS to delegate the CA to the GS. However, the same individual cannot perform CA on TP for moderate complexity testing unless they can qualify as a TC. Therefore, if a laboratory performs both moderate and high complexity testing, a GS can only perform CA on moderate complexity TP if they can meet the regulatory requirements of a TC. This proposed change would allow individuals with applicable associate degrees to assess competency in laboratories that perform both moderate and high complexity testing and bring parity to who performs CA for all nonwaived laboratories while maintaining the laboratory's ability to produce accurate and reliable testing.

At § 493.1411(b), we are proposing to add a requirement at paragraph (b)(6) to allow individuals who are qualified under § 493.1411(b)(1), (2), (3), or (4) or have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution and have at least 2 years of laboratory training or experience, or both, in blood gas analysis to qualify as TC for blood gas testing only. Most blood gas testing was categorized as high complexity when the original regulations were finalized in the 1992 final rule with comment period. Due to improved technology, most routine blood gas testing is now categorized as moderate complexity. We are proposing this change because we believe that it would provide adequate oversight of moderate complexity blood gas testing. Adding this provision specific to TCs in the area of blood gas testing would allow individuals to qualify as a TC in this specific area of expertise. Please note that we will still not consider a degree in respiratory therapy or cardiovascular technology to be equivalent to a biological or chemical science degree. An individual with these qualifications should be able to oversee the testing and CA of personnel performing blood gas testing.

At § 493.1411(b)(7), we are proposing to add a grandfather provision to include those already qualified prior to the date of the final rule, including nurses.

7. Testing Personnel Qualifications (§ 493.1423)

We are proposing to redesignate § 493.1423(b)(2), (3), and (4) as § 493.1423(b)(4), (5), (6), respectively.

We are also proposing to separate current paragraph (b)(1) into two separate provisions. Revised paragraph (b)(1) would include the current requirement of a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located. New paragraph (b)(2) would include the requirement of an earned doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution. As discussed in section II.B.16. of this proposed rule, we are proposing to remove an earned doctoral, master's, or bachelor's degree in ''physical science'' as a means to qualify. In addition, we are proposing to add an earned doctoral, master's, or bachelor's degree in nursing as a means to qualify. In Survey and Certification memo 16–18–CLIA,[14] we stated that ''a bachelor's in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity TP'' and that ''an associate's degree in nursing meets the requirement of having earned an associate's degree in a biological science for moderate complexity TP.'' We appreciate all comments received in response to the 2018 RFI and agree that a nursing degree is not equivalent to a biological or chemical science degree. We also concur with some commenters' recommendation that nursing degrees be used as a separate qualifying degree for TP. As testing practices and technologies have evolved, point of care testing has become a standard of practice in many health care systems, allowing laboratory results to be delivered to the treating health care provider as rapidly as possible. We recognize that in many health care systems, nurses perform the majority of the point of care testing in many different scenarios (for example, bedside, surgery centers, end-stage renal disease facilities). We do not have any reason to believe that nurses would be unable to accurately and reliably perform moderate and high complexity testing with appropriate training and demonstration of competency.

We are proposing to add new paragraph (b)(3) to include the requirement that the individual must meet the criteria in § 493.1405(b)(3)(ii) or (b)(4)(ii) or (iii) or (b)(5)(ii) to allow individuals who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TP using the educational algorithm. See discussion in section II.B.3. of this proposed rule.

In addition, we are proposing to add at paragraph (b)(7) a requirement to allow individuals for blood gas testing to be qualified under § 493.1423(b)(1) through (4) or have earned a bachelor's degree in RT or cardiovascular

[14] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-16-18.html?DLPage=1&DLEntries=10&DLFilter=16-18&DLSort=3&DLSortDir=descending.*

technology from an accredited institution or have an AA related to pulmonary function and have at least 2 years training or experience or both in blood gas analysis. We are proposing this addition so that parity can exist with high complexity TP requirements for blood gas testing at § 493.1489(b)(6). See previous discussion at § 493.1411(b).

8. Laboratory Director Qualifications (§ 493.1443)

As discussed in section II.B.3. of this proposed rule, we are proposing to amend § 493.1443(b)(1)(ii) by removing ''or possess qualifications that are equivalent to those required for such certification.'' As discussed in the above section of this proposed rule, we are proposing to amend § 493.1443(b)(2) by removing the residency requirement at paragraph (b)(2)(i) as a means to qualify and redesignating paragraph (b)(2)(ii) (which requires the individual to have at least 2 years of experience directing or supervising high complexity testing) as paragraph (b)(2)(i). As discussed in section II.B.3. of this proposed rule, we are also proposing to add new paragraph (b)(2)(ii) to require 20 CE credit hours.

We are also proposing to redesignate current paragraph (b)(3)(i) as new paragraph (b)(3)(iii) and to redesignate the provisions of paragraphs (b)(2)(ii)(A) and (B) as new paragraph (b)(3)(iv).

As discussed in section II.B.16. of this proposed rule, we are proposing to redesignate the introductory text of paragraph (b)(3) as new paragraph (b)(3)(i) to revise this paragraph by removing an earned doctoral, master's, or bachelor's degree in ''physical science'' as a means to qualify. As discussed in section II.B.3. of this proposed rule, we would revise newly redesignated paragraph (b)(3)(i) by adding an earned doctoral, master's, or bachelor's degree in ''medical technology'' as a means to qualify.

As discussed in section I.D.1.c. of this proposed rule, we are proposing to add an educational requirement at new paragraph (b)(3)(ii) that includes a qualification algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology.

At paragraphs (b)(3)(ii) and (b)(4) and (5), we are proposing to delete these paragraphs to remove the grandfather provisions as these requirements had to have been met by February 24, 2003, March 14, 1990, and February 28, 1992, respectively, and individuals can no longer qualify under these provisions. We are proposing to add new paragraph (b)(4) to specify the new grandfather provision. We are also proposing to redesignate paragraph (b)(6) as new paragraph (b)(5).

Finally, as discussed in section II.B.3. of this proposed rule, we are proposing to add a 20 CE credit hour requirement at new paragraph (b)(3)(v).

9. Laboratory Director Responsibilities (§ 493.1445)

For proposals related to § 493.1445, please see the discussion at II.B.5. of this proposed rule.

10. Technical Supervisor Qualifications (§ 493.1449)

At § 493.1449, we are proposing to combine the provisions of paragraphs (c) through (g) into new paragraph (c) and combine paragraphs (h) through (j), (n), and (q) into new paragraph (d). We are also proposing to redesignate paragraphs (k), (l), (m), (o), and (p) as paragraphs (e), (f), (g), (h), and (i), respectively. We propose to make these changes to simplify the regulations by reducing confusion and grouping identical TS requirements into a combined provision. We are also proposing to insert the education algorithm at paragraph (c)(4)(i)(B).

At newly redesignated paragraph (e)(1)(ii)(B) (formerly paragraph (k)(1)(ii)(B)), we are proposing to remove and reserve this paragraph since the American Society of Cytology has not provided certification for cytology since 1998; certification is provided by American Board of Pathology and American Board of Osteopathic Pathology.

At newly redesignated paragraph (d) (formerly paragraph (q)), we are proposing to amend the immunohematology requirement for the TS requirement to align with other TS qualifications and allow individuals with doctoral, master's, and bachelor's degrees with appropriate training and experience to qualify as a TS for immunohematology. This provision will be included in § 493.1449(d). The current regulation requires that the TS for immunohematology be a doctor of medicine or osteopathy. Fulfilling the CA requirements (for example, direct observation) can be challenging in rural facilities as the TS may not be onsite as the individual(s) may cover a large geographic area. Often a MT/CLS with a SBB (Specialist in Blood Bank) from ASCP (American Society for Clinical Pathology) [15] is on-site to oversee the day-to-day operations of the blood bank. By allowing qualified individuals with doctoral, master's, or bachelor's degrees, to qualify as TSs, the personnel responsibilities will align with the current practices in laboratories without affecting the ability of the laboratory to provide accurate and reliable results. Further, this proposed change may help alleviate a shortage of physicians in rural areas and does not constitute a risk to public health or the individuals served by the laboratory.

As discussed in section II. B.16. of this proposed rule, we are proposing at § 493.1449 to remove an earned doctoral, master's, or bachelor's degree in ''physical science'' as a means to qualify.

11. General Supervisor Qualifications (§ 493.1461)

As discussed in section II. B.16. of this proposed rule, we are proposing at § 493.1461(c)(1)(i) to remove an earned doctoral, master's, or bachelor's degree in ''physical science'' as a means to qualify. At § 493.1461(c)(3) through (5), we are proposing to delete the grandfather provisions as these requirements had to have been met by February 28, 1992, April 24, 1995, and September 1, 1992, respectively, and individuals can no longer qualify under these provisions. We plan to grandfather all individuals qualified under this provision. We are also proposing to add new paragraph (c)(3) to specify a new grandfather provision for those individuals who had qualified prior to the publication of the final rule.

12. General Supervisor Qualifications on or Before February 28, 1992 (§ 493.1462)

At § 493.1462, we are proposing to remove the grandfather provision as this requirement must have been met by February 28, 1992. These individuals would be included in the grandfather provision for § 493.1461(c)(3) through (5).

13. General Supervisor Responsibilities (§ 493.1463)

At § 493.1463(b)(4), we are proposing to revise the language stating the need to annually evaluate and document the performance of all testing personnel to now require the evaluation and documentation of the competency of all testing personnel. Historically, CLIA has allowed the TS to delegate all CA to the GS. However, the current regulations only speak to the ability of the GS to perform annual CA. We are clarifying that the GS may be delegated both the semi-annual and the annual CA.

[15] *https://www.ascp.org/content/docs/default-source/boc-pdfs/exam-content-outlines/ascp-boc-us-procedures-book-web.pdf.*

14. Cytotechnologist Qualifications (§ 493.1483)

At §§ 493.1483(b)(2) and 493.1489(b)(2)(ii)(B)(*1*), we are proposing to replace ''CAHEA'' with CAAHEP (Commission on Accreditation of Allied Health Education Programs) and to remove, ''or other organization approved by HHS.'' In October 1992, the American Medical Association (AMA) announced its intent to support the establishment of a new and independent agency to assume the accreditation responsibilities of the Commission on Allied Health Education Accreditation (CAHEA), which is CAAHEP. HHS has no approval process for programs not approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES) or CAAHEP.

At § 493.1483(b)(3) through (5), we are proposing to remove the grandfather provisions as these requirements had to have been met by September 1, 1992, or September 1, 1994, as individuals can no longer qualify under these provisions. We plan to grandfather all individuals qualified under this provision prior to the date of the final rule. These individuals would be included in the new grandfather provision at § 493.1483(b)(3).

15. Testing Personnel Qualifications (§ 493.1489)

We are proposing to remove paragraph (b)(3) as the February 28, 1992 grandfather provision must have been met by February 28, 1992. We are also proposing to redesignate paragraphs (b)(2)(i) and (ii) to paragraphs (b)(3)(i) and (ii), respectively. As noted, at § 493.1489(b)(2)(ii)(B)(*1*), we are proposing to replace ''CAHEA'' with ''CAAHEP'' and to remove ''or other organization approved by HHS.''

In addition, we are proposing to revise paragraph (b)(1) to separate the provisions into two paragraphs (that is, paragraph (b)(1) and new paragraph (b)(2)(i)). New paragraph (b)(1) would include the current requirement of a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located. New paragraph (b)(2)(i) would include an earned doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution. As discussed in section II.B.16. of this proposed rule, we are proposing to remove an earned doctoral, master's, or bachelor's degree in ''physical science'' as a means to qualify. We are also proposing to add an earned doctoral, master's, or bachelor's degree in nursing as a means to qualify (see discussion at § 493.142 in section II.B.7. of this proposed rule). In addition, we are proposing to add new paragraph (b)(2)(ii) to state who may be qualified under § 493.1443(b)(3) or § 493.1449(c)(4) or (5) to allow individuals who do not have a chemical, biological, or clinical science or medical technology or clinical laboratory science degree to be eligible to qualify as a TC using the educational algorithm.

At § 493.1489(b)(4), we are proposing to amend this requirement by moving the military provision out of the April 24, 1995, grandfather provision and make it a mechanism that individuals will be able to qualify to be equivalent to the already existing provision in moderate complexity testing (§ 493.1423(b)(3)). We believe these individuals have the requisite educational background to meet the requirements to perform laboratory testing under CLIA. In addition, we are proposing to remove paragraph (b)(4) introductory text and paragraph (b)(4)(i) [the text that currently states ''On or before'' through ''graduated from a [ML] or [CL] training program approved or accredited by ABHES, CAHEA, or other organizations approved by HHS''] per the discussion under § 493.1483(b)(2). As a result, the current military requirement at paragraph (b)(4)(ii) would be redesignated as paragraph (b)(4).

16. Technologist Qualifications on or Before February 28, 1992 (§ 493.1491)

The current language at § 493.1491(b)(6) is being included in the grandfather at § 493.1489(b)(5). We are proposing to remove § 493.1491 as individuals can no longer qualify under this provision.

17. Proposed Removal of Earned Degree in Physical Science as an Educational Requirement

At §§ 493.1405, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, and 493.1489, we are proposing to remove ''physical science'' and add a new educational requirement for the ability to qualify based on semester hours. We concur with CLIAC's recommendation that a degree in physical science should be removed from the CLIA regulations as it is too broad and may not include relevant laboratory science coursework. It is a broad discipline often described as the study of nonliving systems, such as astronomy, physics, and earth sciences. Generally, these types of degrees are not related to clinical laboratory testing. Due to variation in usage and the absence of universally accepted definitions, a ''physical science degree'' is difficult to define for regulatory purposes. We believe that the proposed semester algorithm will allow individuals to qualify in the absence of a traditional chemical, biological, or clinical laboratory science or medical technology degree. An individual graduating with a physical science degree may or may not have sufficient course experience to meet the educational requirement, so the degree alone should not be listed among those that satisfy the educational requirement. We note that in some instances, individuals with these types of degrees have been able to qualify as high complexity TP under § 493.1489 and GSs under § 493.1461(b)(2) as long as they have the applicable training or experience (see section I.D.1.c. of this proposed rule).

18. Clinical Laboratory Science and Medical Technology

At §§ 493.1405(b)(3) and (b)(5)(i), 493.1411(b)(4) and (6), 493.1443(b)(3)(i), and 493.1449(c)(3)(i), (c)(5)(i), (d)(3)(i), (d)(5)(i), (h)(2)(i), and (i)(2)(i), we are proposing to remove any text referring to ''medical technology'' degrees and replace such text with references to degrees in ''clinical laboratory science and medical technology'' so that the latter phrase appears consistently throughout subpart M. Originally, degrees were given in medical technology, however; the naming convention for medical technology degrees has changed since the regulations were first published in the 1992 final rule with comment period. The degree is now referred to as clinical laboratory science. A clinical laboratory science degree is synonymous with a medical technology degree.

C. Proposed Change to CLIA Requirements for Alternative Sanctions for CoW Laboratories

As discussed in section I.C. of this proposed rule, we are proposing to amend § 493.1804(c)(1) by removing the phrase ''(CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)''.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 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.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) of the PRA 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 burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A) required issues for the following information collection requirements (ICRs).

The requirements and burden will be submitted to OMB under OMB Control Number 0938–0612, which expires January 31, 2024. The information collection will be revised to account for the burden.

A. CLIA Fees

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Histocompatibility, Personnel, and Alternative Sanctions

1. Laboratory Costs To Update Policies and Procedures

If this rule is finalized, we expect that the 34,082 CoC and CoA laboratories would incur costs for the time needed to review the revised personnel regulations and update their policies and procedures to be in compliance. The total one-time burden per laboratory to review and update affected policies and procedures is 5 to 7 hours. A management level employee (11–9111) would perform this task at an hourly wage of $557.61 per hour as published by the 2021 Bureau of Labor Statistics.[16] The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from $19,634,640 to $27,488,496 (34,082 laboratories × 5- or 7-hours × $115.22).

Similarly, we expect that the 31,982 PPM laboratories would incur costs for the time needed to review and update the one change clarifying the requirement for CAs in PPM laboratories. We assume a one-time burden of 0.25 to 0.5 hours per laboratory for this task (31,982 × 0.25 or 0.5 hours). A management level employee (11–9111) would perform this task at an hourly wage of $57.61 per hour as published by the 2021 Bureau of Labor Statistics.[17] The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from would range from $921 to $1,842,483 (31,982 laboratories × 0.25- or 0.5-hours × $115.22).

If finalized, the changes to the histocompatibility requirements would affect approximately 218 laboratories that perform testing in this specialty. The laboratories may need to make additional changes to their policies and procedures for the histocompatibility updates. We assume a one-time cost of 1 to 2 hours per laboratory for this task (218 × 1 or 2). A management level employee (11–9111) would perform this task at an hourly wage of $57.61 per hour as published by the 2021 Bureau of Labor Statistics.[18] The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from would range from $25,118 to $50,236 (218 laboratories × 1- or 2-hours × $115.22).

2. Accreditation Organization and Exempt State Costs To Update Policies and Procedures

If the proposed changes are finalized, seven approved accrediting organizations and two exempt states would have to review their policies and procedures, provide updates and submit the changes to CMS for approval (9 organizations/exempt states × 10 or 15 hours). We assume a one-time cost of 10 to 15 hours to identify the applicable legal obligations and to develop the policies and procedures needed to reflect the new requirements for personnel and histocompatibility. A management level employee (11–9111) would perform this task at an hourly wage of $57.61 per hour as published by the 2021 Bureau of Labor Statistics.[19] The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from would range from $10,370 to $17,283 (9 × 10- or 15 hours × $115.22).

Table 9 reflects the total burden and associated costs for the provisions included in this proposed rule.

TABLE 9: Summary of All Costs for Collection of Information in this Proposed Rule

Information Collection Requests*	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
A. Laboratory Costs to Update Policies and Procedures		
CoC/CoA	+7	$27,488,496
PPM	+0.5	$728,185
Histocompatibility	+2	$50,236
B. Accreditation Organization and Exempt State Costs to Update Policies and Procedures	+15	$17,283
TOTAL	**+24.5**	**+28,284,200**

*All costs reflected in this table are one-time only costs. There are no ongoing costs.

[16] *https://www.bls.gov/oes/tables.htm.*

[17] *https://www.bls.gov/oes/tables.htm.*

[18] *https://www.bls.gov/oes/tables.htm.*

[19] *https://www.bls.gov/oes/current/oes_nat.htm.*

V. 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 preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

1. CLIA Fees

As discussed in section I. of this proposed rule, when CLIA was enacted and its implementing regulations were finalized in 1992, CLIA fees were established based on estimates as to the average time a survey would take, cost of the surveyor salary per hour, as well as the size of the laboratory (schedules A, B, etc.). As discussed in section II. of this proposed rule, we are proposing to increase certain CLIA fees, add new CLIA fees, and institute a biennial fee increase based on our analysis of the overall level of collections relative to the costs of maintaining the CLIA program, which project a shortfall beginning in calendar year 2023.

2. Histocompatibility, Personnel, Alternative Sanctions

This rule also proposes to update the CLIA regulations concerning histocompatibility (§ 493.1278), personnel (§§ 493.1351 through 493.1495), and alternative sanctions for laboratories operating under a CoW (*§ 493.1804*). With few exceptions, no changes have been made to the requirements listed above since the CLIA regulations were finalized in the 1992 final rule with comment period (57 FR 7002). Many changes have occurred in the practice of laboratory medicine since that time, and other parts of the regulations have since been updated to eliminate redundancies and streamline requirements. HHS assessed the need to update the sections addressed in this proposed rule and solicited public input via the 2018 RFI (83 FR 1004) and advice from the CLIAC (*www.cdc.gov/cliac/past-meetings.html*) before making decisions about the changes to propose.

Because the specialty of histocompatibility is an evolving area of the clinical laboratory, several changes were made to update and clarify the histocompatibility requirements finalized in the 2003 final rule (68 FR 3640). Since then, there have continued to be advancements in histocompatibility testing. As a result, some requirements have become obsolete and may preclude using current, improved methods and practices. As already mentioned, there have been updates to other parts of the CLIA regulations to eliminate redundancy with general quality system requirements. However, changes to eliminate redundancy have not previously been made in the histocompatibility specialty, which we believe would simplify and streamline the regulations. Thus, we propose eliminating redundant histocompatibility specialty regulations in this proposed rule.

Provisions to end a phase-in period, previously included in subpart M, that allowed individuals with an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science to meet the qualification requirements for LD of high complexity testing prior to obtaining board certification, were finalized in the 2003 final rule (68 FR 3640). This rule also revised and expanded the qualifications required for such individuals to direct a laboratory performing high complexity testing. No other changes have been made to clarify or update subpart M since 1992, even though the top 10 laboratory deficiencies have historically continued to include qualification requirements and responsibilities for moderate and high complexity LD. These high numbers of deficiencies may be due, in part, to the redundancy throughout subpart M or to requirements that are unclear, both of which may be an ongoing source of confusion for laboratories and individuals seeking to determine their qualification status. The number of deficiencies may also be due to laboratories whose directors are on-site infrequently or not at all.

The CLIA requirements at § 493.1804 describe general considerations for the imposition of sanctions under the CLIA program. This includes principal or alternative sanctions as described in § 493.1804(c). This section specifies that alternative sanctions are not imposed on laboratories issued a CoW, but discretion is permitted in applying principal or alternative sanctions to laboratories issued other certificate types. Since the CLIA statute at 42 U.S.C. 263a(h) does not make this distinction concerning alternative sanctions, we found that § 493.1804(c) can be updated to reflect CMS' belief that alternative sanctions instead of principal sanctions should be an option to create parity for all certificate types. In some cases, we believe the imposition of principal sanctions on CoW laboratories is not appropriate and could create an undue burden on these laboratories that do not currently have the option of receiving alternative sanctions, if appropriate, as laboratories with other certificate types.

In summary, we based our decision to update our regulations at § 493.1278 related to histocompatibility on changes in practice, advice from the CLIAC, and responses to the 2018 RFI. We based our decision to update the personnel requirements in subpart M, §§ 493.1351 through 493.1495, and propose changes in this rule to delete obsolete and redundant regulations and to clarify this subpart specifying personnel qualifications and responsibilities on advice from CLIAC, common questions we have received, and responses to the 2018 RFI. We based our decision to update our regulation at § 493.1804(c) to allow for alternative sanctions to be imposed on CoW laboratories on responses received to the 2018 RFI.

B. Overall Impact

We have examined the potential impacts of this 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 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) (having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the

rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory actions and/or economically significant effects ($100 million or more in any one year). The regulation is not economically significant within the meaning of section 3(f)(1) of the Executive order since neither the low estimate: $28,145,841 nor the high estimate: $57,528,591 exceeds the $100 million annual threshold.

This proposed rule increases certain CLIA Fee requirements and will affect approximately 265,335 clinical laboratories, resulting in some budget implications. However, since laboratories, accrediting organizations, and exempt states will need to make changes to comply with the Federal regulatory changes, we have provided an assessment of the impact of estimated costs of these changes in Table 14.

The Regulatory Flexibility Act (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 the great majority of clinical laboratories and AOs are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). For purposes of the RFA, approximately 82 percent of clinical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet, updated January 2021 (*https://www.aha.org/statistics/fast-facts-us-hospitals*), and 100 percent of the AOs are nonprofit organizations. Individuals and states are not included in the definition of a small entity. While a significant number of clinical laboratories and accrediting agencies are affected by this rule, the impact is not economically significant. It is anticipated that the benefits obtained by ensuring quality laboratory testing will outweigh the costs. See Table 10. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities. We are voluntarily preparing a Regulatory Impact Analysis, including both a qualitative and quantitative analysis, and are requesting public comments on the impacts to assist us in making this determination in the final rule.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital located outside a metropolitan statistical area with fewer than 100 beds. There are approximately 905 small rural hospitals in the U.S. Such hospitals often provide limited laboratory services or may refer all their testing to larger facilities. We are unable to estimate the number of laboratories that support small rural hospitals and do not expect that the rule will have a significant impact on small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold was approximately $158 million. We do not anticipate this proposed rule would impose an unfunded mandate on states, tribal governments, and the private sector of more than $158 million annually. We request comments from states, tribal governments, and the private sector on this assumption.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Two states have exempt status, which means we have determined that the state has enacted laws relating to the laboratory requirements that are equal to or more stringent than CLIA requirements, and the state licensure program has been approved by us. If this rule is finalized, the two states, New York and Washington, would need to update their policies and procedures to maintain their exempt status but would otherwise not incur additional costs. Therefore, this proposed rule would not have a substantial direct effect on state or local governments, preempt states, or otherwise have a federalism implication, and there is no change in the distribution of power and responsibilities among the various levels of government.

C. Anticipated Effects

Tables 10 and 11 reflect the estimated impact for the provisions included in this proposed rule.

TABLE 10: Summary of Estimated Impact for Proposed Regulations

Proposed Change	Low estimate	High estimate
Laboratories updating policies and procedures related to personnel and histocompatibility	$20,524,180	$29,279,200
Accrediting organizations and exempt states updating policies and procedures related to personnel, histocompatibility, and laboratory director site visit	$10,370	17,283
Travel for site visits-Driving	$150,800	$678,745
Travel for site visits-Flying	$478,400	$956,800
Total Increased cost	$21,163,750	$31,034,043

TABLE 11: Summary of Estimated Impact for Proposed Fee Regulations

Proposed Change	Low estimate	High estimate
CLIA Fee Regulations	$9,144,894	$29,661,467
Total Increased cost	$9,144,894	$29,661,467

1. Fees

This proposed rule impacts approximately 265,335 CLIA certified laboratories. Certificate of Waiver (CoW) = 201,767; Certificate of Provider Performed Microscopy (PPM) = 29,988; Certificate of Registration (CoR) = 2,826; Certificate of Compliance (CoC) = 17,799; Certificate of Accreditation (CoA) = 15,781. (Data from Quality, Certification and Oversight Reports (QCOR) as of September 27, 2020)

a. Two-Part Biennial Survey Fees

(1) CoC Laboratories Compliance Survey Fees

Table 12 reflects the national average of compliance fees for each classification of laboratories (schedules) that requires inspection. Specifically, Table 12 represents the national average for each schedule for the current Compliance Survey Fees (noted with a ''c'') as paid biennially by laboratories that hold a CoC and the national average for each schedule for the new Compliance Survey Fees (noted with a ''n'') that will be paid after the first biennial two-part fee increase (estimating a 5 percent increase as a low estimate and a 20 percent increase as a high estimate) by laboratories that hold a CoC. As discussed in section II. of this proposed rule, Table 12 shows estimated increases for CoC laboratories subject to the biennial fee increase.

TABLE 12: Two-part fee for CoC Survey Fees*

Laboratory classification (schedules)	Current average (c)	New average (n) Low increase = 5%	New average (n) High increase = 20%	Number of Laboratories per schedule*	Number of Laboratories per schedule divided by 2**
V	$360	$378	$432	6,462	3231
A	$1,192	$1,251.60	$1,430	4,054	2027
B	$1,591	$1,670.55	$1,909	147	73.5
C	$1,988	$2,087.40	$2,386	2.032	1.016
D	$2,336	$2,452.80	$2,803	176	88
E	$2,684	$2,818.20	$3,221	1,427	713.5
F	$3,032	$3,183.60	$3,638	815	407.5
G	$3,380	$3,549	$4,056	517	258.5
H	$3,728	$3,914.40	$4,474	1,733	866.5
I	$4,076	$4,279.80	$4,891	195	97.5
J	$4,408	$4,628.40	$5,290	189	94.5

*Number of CoC labs by laboratory classification (schedules) (Data from Certification and Survey Provider Enhanced Reporting (CASPER) 0086S CLIA Laboratories Schedule Counts) Includes CoR labs of application type CoC.

**The fees are biennial; therefore, approximately half the CoC laboratories are affected annually.

(2) CoA Laboratories Validation Survey Fees

Table 13 shows the national average of the Validation Survey Fee for each schedule of accredited laboratory. Specifically, Table 13 represents the national average fees for each schedule for the current Validation Survey Fee (noted with a ''c'') as paid biennially by laboratories that hold a CoA and the national average for the new Validation Survey Fee (noted with an ''n'') that will be paid the first biennial two-part fee increase (estimating a 5 percent increase as a low estimate and a 20 percent increase as a high estimate) by laboratories that hold a CoA. As discussed in section II. of this proposed rule, Table 13 shows estimated increases for CoA laboratories subject to the biennial fee increase.

TABLE 13: Two-part fee for Certificate of Accreditation (CoA) Validation Survey Fees*

Laboratory classification (schedules)	Current average (c)	New average (n) 5%	New average (n) 20%	Number of laboratories per schedule*	Number of Laboratories per schedule divided by 2**
V	$18	$18.9	21.6	2,108	1054
A	$60	$63	72	2,522	1261
B	$80	$84	96	135	67.5
C	$99	$103.95	118.8	1,739	869.5
D	$117	$122.85	140.4	189	94.5
E	$134	$140.7	160.8	1,524	762
F	$152	$159.6	182.4	900	450
G	$169	$177.45	202.8	612	306
H	$186	$195.3	223.2	3,043	1521.5
I	$204	$214.2	244.8	1,098	549
J	$220	$231	264	1,914	957

*Number of CoA labs by laboratory classification (schedules) (Data from CASPER 0086S CLIA Laboratories Schedule
Counts) Includes CoR labs of application type CoA.
**The fees are biennial; therefore, approximately half the CoA laboratories are affected annually.

(3) Certificate of Waiver (CoW) Waived Test Categorization Certificate Fee

Table 14 shows the additional fee to be added to Certificates of Waiver (CoW) to offset program obligations to FDA for its role in the categorization of tests and test systems as waived. Specifically, Table 14 represents the certificate fee (noted with a ''c'') as paid biennially by laboratories that hold a CoW and the new certificate Fee (noted with an ''n'') that will be paid by laboratories that hold a CoW using the current number of CoW labs for the low estimate and the current number plus 10,000 new CoW for the high estimate. As discussed in section II. of this proposed rule, Table 14 reflects a total increase of $25 as each laboratory's part of the Waived test categorization fee.

TABLE 14: Certificate of Waiver (CoW) Waived Test Categorization Fee*

Type of CLIA certificate	Current Fee (c)	New Fee (n) based on current number of CoW labs
Certificate of Waiver (CoW)	$180	$205

*Total CoW labs as of 9-27-2020 = 201,767 / 2 = 100,883.50 (data from QCOR) for the low estimate. Addition of 10,000 new CoW labs 211,767/2 = 105,883.50 for the high estimate. The fees are biennial; therefore, approximately half the CoW laboratories are affected annually.

(4) Two-Part Biennial Certificate Fees

Table 15 shows the national average of the certificate fee for each schedule for the CoC and CoA laboratories and shows the CoW, PPM, and CoR certificate fees. Specifically, Table 15 represents the national average fees for each schedule for the CoC and CoA Certificate Fee and the CoW, PPM, and CoR (noted with a ''c'') as paid biennially by laboratories that hold a CoC, CoA, CoW, PPM, or CoR and the national average fees for each schedule for the new CoC and CoA Certificate Fee and the CoW, PPM, and CoR (noted with an ''n'') that will be paid after the first biennial two-part fee increase (using 5 percent to arrive at a low estimate and 20 percent to arrive at a high estimate) by laboratories that hold a CoC, CoA, CoW, PPM, or CoR. As discussed in section II. of this proposed rule, Table 15 reflects estimated increases for all laboratory types subject to the biennial fee increase.

TABLE 15: Two-part Biennial Certificate Fee

Type of CLIA Certificate	Laboratory schedule	Current fee (c)	New fee (n) using 5% for the low estimate	New fee (n) using 20% for the high estimate	Number of laboratories*		Number of Laboratories divided by 2**	
Certificate of Waiver (CoW)	Not applicable	$205.00	$215.25	246.00	201,767		100,883.5	
Certificate of Provider Performed Microscopy (PPM)	Not applicable	$240.00	$252.00	288.00	29,988		14,994	
					CoC	CoA	CoC	CoA
Certificate of Compliance (CoC) and Certificate of Accreditation (CoA)	V	$180.00	$189.00	216.00	6,462	2,108	3231	1054
CoC and CoA	A	180.00	189.00	216.00	4,054	2,522	2027	1261
CoC and CoA	B	180.00	189.00	216.00	147	135	73.5	67.5
CoC and CoA	C	516.00	541.80	619.20	2,032	1,739	1,016	869.5
CoC and CoA	D	528.00	554.40	633.60	176	189	88	94.5
CoC and CoA	E	780.00	819.00	936.00	1,427	1,524	713.5	762
CoC and CoA	F	1,320.00	1,386.00	1,584.00	815	900	407.5	450
CoC and CoA	G	1,860.00	1,953.00	2,232.00	517	612	258.5	306
CoC and CoA	H	2,448.00	2,570.40	2,937.60	1,733	3,043	866.5	1521.5
CoC and CoA	I	7,464.00	7,837.20	8,956.80	195	1,098	97.5	549
CoC and CoA	J	9,528.00	10,004.40	11,433.60	189	1,914	94.5	957
Certificate of Registration (CoR)	Not applicable	$100	$105	120.00	2,826		1,413	

*Number of laboratories from QCOR and CASPER 0086S CLIA Laboratories Schedule Counts.
**The fees are biennial; therefore, approximately half the CoA laboratories are affected annually.

b. Proposed New Replacement and Revised Fees

Table 16 shows the cost of the replacement and revised certificate fees for each certificate type. These fees have not been charged prior to this proposed rule. A low estimate used the current number of laboratories and a high estimate used the number of labs plus half again that amount.

TABLE 16: CLIA Replacement and Revised Certificates FY2019*

Certificate type	Number of Replacement Certificates issued in FY2019	Cost of Replacement Certificate	Number of Revised Certificates issued in FY2019	Cost of Revised Certificate
CoC	259	$75	515	$150
CoW	2,824	$75	6,985	$95
CoA	496	$75	505	$150
PPM	525	$75	984	$95
Total:	4104	$75	8989	$150

* Number of Replacement and Revised Certificates FY2019 (Data from CASPER 0104D CLIA 116 Activity report).

c. New Additional Fees

Table 17 shows the cost of the additional fees added by this proposed rule. These fees are only paid by laboratories with substantiated complaint surveys, unsuccessful performance of PT, or follow-up surveys for the determination of correction of deficiencies found on an original survey.

TABLE 17: New Additional Fees

Proposed Fees	Affected CLIA Certificate type(s)	Total Number of Affected Laboratories *	Hourly Cost	Occupation	Hours		Range of Cost Estimate for Proposed new fees per incident	
					Low	High	Low Estimate	High Estimate
Substantiated Complaints	All Laboratory types	56	$150.22 [1]	13-1041 43-1011 43-9199	5.00	184.75	$751.10	$27,753.15
Unsuccessful Proficiency Testing (PT)	Certificate of Compliance (CoC) laboratories	1,308	$150.22	13-1041 43-1011 43-9199	1.25	32.25	$187.78	$4,844.60
Follow-up Surveys[2]	Certificate of Compliance (CoC) & Certificate of Accreditation (CoA) laboratories	225	$150.22	13-1041 43-1011 43-9199	8.65	19.08	$1,299.40	$2,866.20
Total Estimated Cost							$2,238.30	$35,463.95

*Total number of affected laboratories is based on actual numbers from FY2019; Data from CASPER reporting system.
[1]$75.11 hourly rate includes $27.79 (13-1041: Compliance Officer) + $28.91 (43-1011: First-Line Supervisors of Office and Administrative Support Workers) + $18.41 (43-9199: Office and Administrative Support Workers, All Other). The wage rate would be doubled to $150.22 to include overhead and fringe benefits. Data from the Department of Labor.
[2]Includes Follow-up surveys on CoC and CoA laboratories and for Addition of Specialties.

d. Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories

This proposed rule, if finalized, could impact all of the 271,399 CLIA-certified laboratories (accessed from the CMS Quality Improvement Evaluation System (QIES) database October 4, 2019) to some extent. The changes to the personnel requirements would impact 34,082 CoC and CoA laboratories, as well as 31,982 PPM Certificate laboratories. The histocompatibility changes would impact 218 CoC and CoA laboratories certified for this specialty; and the allowance for alternative sanctions could impact 201,767 CoW laboratories only if they are found to be out of compliance with CLIA and subject to sanctions. The proposed rule, if finalized, would also impact the seven CLIA-approved AOs and two exempt states. Although complete data are not available to calculate all estimated costs and benefits that would result from the changes proposed in this rule, we are providing an analysis of the potential impact based on available information and certain assumptions. Implementation of these proposed requirements in a final rule would result in changes that are anticipated to have both quantifiable and non-quantifiable impacts on laboratories, AOs, and exempt states, as specified above. In estimating the quantifiable impacts, we include costs to CoC, CoA, and PPM laboratories that could result from the need to update policies and procedures. We also estimate costs for travel expenses that laboratories may incur to meet the proposed requirement to have an LD on-site at least once every 6 months. For quantifiable impacts on AOs and exempt states, we estimate the costs for updating their policies and procedures to reflect the new requirements, if finalized, for personnel and histocompatibility.

2. Quantifiable Impacts

a. Laboratory Costs To Update Policies and Procedures

If this rule is finalized, we expect that the 33,580 CoC and CoA laboratories would incur costs for the time needed to review the revised personnel regulations and update their policies and procedures to be in compliance with them. We assume a one-time burden of 5 to 7 hours per laboratory to review and update affected policies and procedures, and we assume the person performing this task would be a management level employee paid $115.22 per hour (wages, salary and benefits; *www.bls.gov/news.release/ecec.t02.htm*). Therefore, we estimate the one-time costs for CoC and CoA laboratories to update policies and procedures to comply with the revised personnel requirements would range from $19,634,640 to $27,488,496 (see Table 18).

Similarly, we expect that the 29,998 PPM laboratories would incur costs for the time needed to review and update the one change clarifying the requirement for CAs in PPM laboratories. We assume a one-time burden of 0.25 to 0.5 hours per laboratory for this task, also to be performed by a management level employee paid $115.22 per hour (wages, salary and benefits). Therefore, we estimate the one-time costs for PPM laboratories to update the single revised policy and procedure to comply with the personnel requirements would range from $864,092 to $1,728,185 (see Table 18).

If finalized, the changes to the histocompatibility requirements would affect approximately 218 laboratories that perform testing in this specialty (QIES database October 4, 2019). While these laboratories are included in the calculations above, they may need to make additional changes to their policies and procedures for the histocompatibility updates, if the proposed rule is finalized. We assume a

one-time burden of one to two hours per laboratory for this task, as described above. Therefore, the laboratory costs for updating policies and procedures related to histocompatibility would range from $25,118 to $50,236 (see Table 18).

b. Accreditation Organization and Exempt State Costs To Update Policies and Procedures

If the proposed changes are finalized, seven approved accrediting organizations and two exempt states would have to review their policies and procedures, provide updates and submit the changes to us for approval. We estimate a one-time burden of 10 to 15 hours to identify the applicable legal obligations and to develop the policies and procedures needed to reflect the new requirements for personnel and histocompatibility. We assume the person performing this review will be a management level employee paid $115.22 per hour (wages, salary and benefits). Therefore, we estimate the costs for accrediting organizations and exempt states to update their policies and procedures would range from $10,370 to $17,283 (see Table 18).

TABLE 18: Estimated Costs to Update Policies and Procedures

Proposed Regulation Change	Affected Group	Total Number of Affected Groups	Hourly Cost	Hours		Range of Cost Estimate for Personnel and Histocompatibility Proposed Changes	
				Low	High	Low Estimate	High Estimate
Personnel	CoC & CoA Laboratories	33,580	$115.22	5	7	$19,634,640	$27,488,496
	PPM Laboratories	29,988	$115.22	0.25	0.50	$864,092	$1,728,185
Histocompatibility	CoC & CoA Laboratories	218	$115.22	1	2	$25,118	$50,236
Personnel, Histocompatibility	Accrediting Organizations and Exempt States	9	$115.22	10	15	$10,370	$17,283
Total Increased Cost						$20,534,220	$29,284,500

c. Laboratory Costs for On-Site Laboratory Director Requirement

Estimating the potential travel costs for LD to meet the on-site requirement is complex, due to wide variation in the numbers of individuals who might incur travel costs, variation in the distances traveled and modes of transportation used, and variation among already existing state and accreditation requirements for LD to be on-site at some frequency. In addition, we had limited available data on which to base our assumptions. Therefore, we used an approach in calculating our estimates such that the estimates described below may be higher than actual costs that would be incurred if the proposed change is finalized. We are requesting public comments and data to assist us in estimating this impact in the final rule.

In general, 11 states, one territory, and three out of seven AOs currently have some requirement for on-site visits by LD, although the required frequencies vary. Ten states, including the exempt state of New York, (Supplemental Table) plus the territory of Puerto Rico currently have requirements that are as stringent or more stringent than the proposed provision that requires a LD to be on-site at least once every 6 months. Therefore, we have not counted CoC laboratories in these 10 states or in Puerto Rico among those that would be impacted if the proposed requirement for on-site LD visits was finalized. One accrediting organization (AABB) now requires on-site LD visits at least once a quarter. However, AABB only accredits 265 laboratories, or approximately 1.6 percent, of all accredited laboratories (QIES database, October 4, 2019). Some of these laboratories are part of a hospital or other health care system that has laboratory specialties accredited for CLIA purposes by one or more of the other accrediting organizations, and therefore, would be impacted by the proposed requirement for on-site LD visits. Since we do not have data to determine the number of such laboratories that are only accredited by AABB and already be meeting this proposed requirement, and the number is likely to be relatively small, we are not adjusting the number of impacted laboratories based on AABB accreditation.

In the 40 states, four territories, and the District of Columbia, where the LD is not required to be on-site at least twice per year, 26,007 CoC and CoA laboratories (QIES, October 4, 2019) may not meet this new requirement, if finalized, and may incur travel costs. We have not adjusted this number where the proposed provision was partially met, since no frequency was specified for CoC laboratories in three additional states, CoA laboratories under two additional accrediting organizations, or laboratories in the exempt State of Washington.

We assume that in most instances, the LD is on-site daily or otherwise more frequently than twice per year. Based on a review of state and AO information, discussed earlier in the preamble for this proposed rule, we assume that between 5 percent (1300) and 20 percent (5201) of the CoC and CoA laboratories would need their LD to travel to the laboratory twice a year to meet this requirement. For our estimate, we assumed this travel would include a combination of two modes of transportation, driving, and flying. For the low estimate, we assumed that 1 percent of the 26,007 laboratories, or

260, would compensate their directors for flights while 4 percent, or 1,040 laboratories, would compensate them for their mileage to drive. For the high estimate, we assumed that, at most, 2 percent of the 26,007 laboratories, or 520, would compensate their LD for flying, and the other 18 percent, or 4,681 laboratories, would compensate for driving.

• *Driving:* We believe most LD would drive fewer than 250 miles round trip to reach the laboratories they direct. We assume these LD would drive to the location, conduct business, and return home the same day. We base our calculations for driving on the maximum estimated distance of 250 miles at $0.58 cents per mile (Government travel reimbursement rates for mileage (*https://www.gsa.gov/travel-resources*)) for a maximum cost of $145.00 per trip. This may be an overestimate since we believe not all the individuals who drive would travel 250 miles round trip. Based on the low estimate of 1,040 laboratories incurring costs for driving and our high estimate of 4,681 laboratories incurring costs for driving, our calculated cost for driving is estimated to range from $150,800 to $678,745 (see Table 19).

• *Flying:* Our estimates for the cost of flying assume that travel to a remote site would be necessary in these cases. We believe basing it on travel to a remote site will over-estimate the cost since in many locations, although the LD may fly to reach their destination, they would not travel to remote locations, and the travel costs would be less. However, we do not know the specific circumstances for which flying would be required. We estimated the maximum airfare for this travel to be $1500 and lodging costs to average $170.00 per night (based on the average of 100 hotel rates throughout the U.S. in 2019 (*https://www.businesstravelnews.com/uploadedFiles/9._Microsites/Corporate_Travel_Index/Corporate_Travel_Index_2019/US_Diem/4-5_USHotelDetail.pdf*)). We assumed lodging for two nights would be needed. Therefore, the estimated cost for one trip would be $1500 flight + $340.00 lodging or $1840.00 per trip. Based on the low estimate of 260 laboratories incurring costs for remote travel and our high estimate of 520 laboratories incurring costs for remote travel, the range for laboratory costs for flying to on-site visits would be between $478,400 and $956,800 (see Table 19).

Based on these assumptions for both driving and flying, if this proposed rule is finalized, we estimate the total cost for laboratories to compensate for LD travel would range from $629,200 to $1,635,545.

TABLE 19: Estimated Travel Costs to Meet On-site Laboratory Director Requirement

Proposed Regulation Change	Affected Group	Total Number of Affected Group		Airfare Cost ($1,500)	Hotel Cost ($170/2 nights)	Driving Cost ($0.58/mile*250 miles)	Total Low Impact for Personnel and Histocompatibility Regulation Changes	
On-Site Laboratory Director	CoA and CoC Laboratories	Low Estimate	High Estimate				Low estimate	High estimate
	Driving	1,040(4%)	4,681(18%)	NA	NA	$145	$150,800	$678,745
	Flying	260 (1%)	520(2%)	$1,500	$340	N/A	$478,400	$956,800
Total Increased Cost							$629,200	$1,635,545

d. Results

We estimate that the overall impact of adding requirements for the proposed changes in personnel, histocompatibility, and travel for LD on-site visits will range from $11,421,708 to $16,983,208 in the first year (see Tables 18 and 19) if these proposed changes are finalized.

For each of the changes, Table 20 shows the projected range of cost estimates annually for 5 years starting in 2020. We assume costs for updating policies and procedures will be one-time costs only incurred in 2021. We presume the travel costs will be ongoing and will not change significantly over the 5-year period. The maximum cost estimate of approximately $16.1 million for the first year based on 2020 costs and approximately $1.6 million for subsequent years is not considered a significant economic impact. This proposed rule does not reach the economic threshold and thus is not considered a major rule. We request comments and additional data to assist us in making a more thorough and accurate prediction of impact of the final rule.

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TABLE 20: Five-Year Projection for Total Estimated Annual Costs for Proposed Histocompatibility and Personnel Regulations

Proposed Change	2023		2024		2025		2026		2027	
	Low	High	Low	High	Low	High	Low	High	Low	High
Laboratories updating policies and procedures related to personnel and histocompatibility	$10,787,073	$15,339,510	$0	$0	$0	$0	$0	$0	$0	$0
Accrediting organizations and exempt states updating policies and procedures related to personnel, histocompatibility, and laboratory director site visit	$5,435	$8,153	$0	$0	$0	$0	$0	$0	$0	$0
Travel-Driving	$150,800	$678,745	$150,800	$678,745	$150,800	$678,745	$150,800	$678,745	$150,800	$678,745
Travel-Flying	$478,400	$956,800	$478,400	$956,800	$478,400	$956,800	$478,400	$956,800	$478,400	$956,800
Total Increased cost	**$11,421,708**	**$16,983,208**	**$629,200**	**$1,635,545**	**$629,200**	**$1,635,545**	**$629,200**	**$1,635,545**	**$629,200**	**$1,635,545**

* Low/high estimates represent the sum of estimates in Table 17 to update policies and Table 18 to estimate travel costs.

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e. Non-Quantifiable Impacts and Benefits

(1) CLIA Fees

CMS has limited knowledge of the non-quantifiable impacts and benefits and is seeking public comment on this topic.

(2) Histocompatibility, Personnel, Alternative Sanctions

If the changes proposed in this rule for histocompatibility, personnel, and alternative sanctions are finalized, several non-quantifiable impacts, most of which are considered benefits, will result for laboratories, accrediting organizations, and exempt states concerning changes in the requirements for personnel, histocompatibility, and alternative sanctions for CoW laboratories. We solicit comments and data to determine quantifiable estimates for these non-quantifiable impacts in the final rule.

Many personnel changes proposed in this rule would decrease the burden and provide greater flexibility for laboratories by increasing the number of eligible candidates for some personnel categories by expanding and clarifying the qualifying degrees. Examples of these proposed changes that would increase the number of qualified candidates for personnel categories include the addition of: clinical nurse specialists and certified registered nurse anesthetists in the definition of midlevel practitioners, a bachelor's degree in respiratory therapy as a possible qualifying degree as a TC and TP for moderate and high complexity blood gas testing, an associate or bachelor of nursing degree as a qualifying degree for moderate complexity TP, and a bachelor of nursing degree as a qualifying degree for high complexity TP. Adding these options as qualifying degrees does not preclude the need for individuals to meet clinical laboratory training and experience requirements. Another proposed personnel change that would decrease burden, increase flexibility for laboratories, and streamline regulations is aligning the technical supervisor qualifications for laboratories performing immunohematology with those of other specialties such as hematology. Instead of limiting those qualified to serve as a technical supervisor in immunohematology to individuals with a doctor of medicine or doctor of osteopathy degree and appropriate certification and experience, if this proposed rule is finalized, individuals may also qualify with a doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology and 1, 2, or 4 years applicable experience, respectively. All of these proposed changes, if finalized, would streamline the regulations and could increase a laboratory's ability to find qualified personnel, especially in rural areas. As it is not possible to predict the pathway a laboratory would use to qualify individuals when hiring personnel, we cannot quantify the impacts that would result. However, we request comments and data to assist us in estimating these impacts in the final rule.

If the rule is finalized, several other changes being proposed in this rule will impact laboratories and their personnel. However, we do not have data to quantify the impact. One proposed change is the qualification requirement for 20 CE credit hours, as defined, to cover LD responsibilities as defined in the regulations prior to serving as an LD. This requirement would apply to LD for both moderate and high complexity testing except for those doctors of medicine, osteopathy, or podiatry who are certified by the American Board of Pathology, the American Osteopathic Board of Pathology, or other boards approved by HHS. Although there would be costs associated with obtaining these credits, currently employed LD, at the effective date of the final rule, will not be required to obtain the 20 CE credit hours to retain their employment status. In the future, we cannot predict the number of laboratories that would choose to hire a LD through the qualification route that would require the 20 CE credit hours. Another proposed change that could impact laboratories that cannot be quantified is the removal of physical science degrees as qualifying degrees for any personnel categories. As stated above, we cannot predict the number of laboratories that may have otherwise chosen to hire personnel with a physical science degree. Currently, employed laboratory personnel, at the effective date of the final rule, will not be disqualified. We request comments and data to assist us in more accurately estimating these impacts in the final rule.

The changes to the histocompatibility requirements proposed in this rule would impact laboratories, accrediting organizations, and exempt states if finalized. This proposed rule would streamline the histocompatibility requirements and remove those that are no longer relevant based on current testing practices, adding flexibility for laboratories and removing perceived barriers to current practices. It would remove specific requirements that are redundant with those covered in general under §§ 493.1251, 493.1252, 493.1256, and 493.1445, simplifying the requirements related to procedure manuals; test systems, equipment, instruments, reagents, materials, and supplies; control procedures; and LD responsibilities. We believe these impacts would decrease the burden and positively affect laboratories certified to perform testing in this specialty, as well as health care providers and patients. We request comments and data to assist us in more accurately estimating the impact of these histocompatibility changes in the final rule.

Last, concerning the alternative sanctions provision being proposed in this rule, when finalized, the rule would allow us discretion in imposing alternative sanctions (that is, civil money penalties (CMP), directed plan of correction, directed portion of a plan of correction, and on-site state monitoring), rather than only being able to impose principal sanctions (that is, revocation, suspension, limitation of the CLIA certificate), in CoW laboratories, if appropriate. We believe this change would increase flexibility, decrease potential burden while moving those laboratories toward compliance, and have no added economic impact on CoW laboratories. As previously described, an example of when this proposed regulatory change could decrease the burden would be in the case of sanctions imposed for improper proficiency testing referral. Although we have no data indicating that principal sanctions have been imposed on CoW laboratories for this reason in the past, if it occurred in the future, the ability to impose alternative sanctions, if appropriate, would be less punitive and potentially decrease any quantifiable economic impact. At this time, we cannot quantify what that impact would be.

D. Alternatives Considered

1. CLIA Fees

We considered multiple options prior to this proposed rule, including limiting across-the- board increase to varying percentages and timeframes required to achieve reasonable carryover targets for the CLIA program as a whole. We discussed multiple options in the notice with comment period (NC), including limiting the increase to varying percentages and timeframes across a single fee type, specifically Compliance Fees. When preparing the NPRM, we reviewed the alternatives in the NC to see if they were viable moving forward. The approach proposed here was the best scenario for longevity for

maintaining the fiscal solvency of the user-funded CLIA program. We have determined that 2 quarters worth of obligations were a reasonable carryover target based on program funding requirements and the time to accumulate and make available current year fee collections. We have also decided to build up to the carryover target over a 3-year period to avoid either overcharging or undercharging. For example, we considered the following options:

- Setting various one-time dollar level fee increases for Certificate of Waiver laboratories.
- Setting various percentage increases for the one-time across-the-board increase.

Public comments received from the 2018 notice with comment period (Medicare Program; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees) [20] were considered during rulemaking. We are also seeking public input on additional alternatives to consider.

2. Histocompatibility, Personnel, Alternative Sanctions

Several alternatives were considered in developing these proposed changes to the histocompatibility, personnel, and alternative sanctions requirements under CLIA. In all cases, one option would be to leave the regulations as written. However, because many of the changes being proposed for histocompatibility and personnel resulted from public input via the 2018 RFI and recommendations made by CLIAC and would add flexibility, remove redundant or obsolete requirements, clarify and streamline the regulations, and decrease burden while maintaining laboratory quality, we perceived that not making these changes would not be preferable. Also, the proposed change to allow alternative sanctions to be imposed on CoW laboratories aligns the regulations with the CLIA statute; therefore, no other options were considered.

Regarding the histocompatibility requirements, we initially considered only removing the crossmatch regulatory requirement at § 493.1278(f)(2) which was perceived as a barrier to current practice with kidney transplantation. However, we decided to obtain input from stakeholders to identify any concerns regarding crossmatching and other current regulatory requirement under the histocompatibility specialty. Our purpose for seeking stakeholder input through CLIAC and the 2018 RFI was to obtain information on whether the current histocompatibility requirements, including requirements for crossmatching, needed to be revised from when CLIA was published in 1998 and 2003 to reflect the current practice. Our proposed revision reflects our attempt to address the inputs from the stakeholders and are intended to reflect the current practices as provided to CMS by the stakeholders through the 2018 RFI and CLIAC.

One of the personnel requirements being proposed is to require that LD of moderate and high complexity testing, who are qualified through an educational pathway other than being a certified anatomic or clinical pathologist, have at least 20 CE credit hours related to their LD responsibilities. We considered requiring this of all LD. However, since pathologists obtain this education as part of their education and training, it would be redundant and could increase costs to require this, although we do not have data to estimate what those costs would be since we do not know how many LD would qualify using this pathway. We believe it is appropriate to propose this requirement for other LD qualification routes. This information is critical for fulfilling LD responsibilities and is not always included in education and training for alternative qualification pathways.

Another LD requirement proposed in this rule is on-site visits to the laboratory at least once every 6 months, with at least a 4-month interval between on-site visits. We considered requiring these visits at a different frequency or not adding this requirement. However, surveyors reported that laboratories in which the director is not on-site tend to have more issues and citations when inspected, and ten states, the territory of Puerto Rico, and one of the CLIA-approved AOs already require LD to be on-site at least once every 6 months. As a result, CLIAC recommended that LD make and document at least two reasonably spaced on-site visits per year to supplement other interactions with staff and verify that the laboratory complies with laws and regulations. We agree with the CLIAC recommendation that two on-site visits per year is an appropriate frequency to achieve the intended improvement in laboratory compliance without adding a significant burden to laboratories. We will monitor this impact if the proposal is finalized. Requiring these visits at a greater frequency and keeping all other factors the same would increase total projected costs for each on-site visit added per year. While requiring on-site visits only once per year would reduce estimated costs, it could delay the potential time it takes to identify laboratory issues that could ultimately result in patient harm. A third personnel requirement proposed in this rule for which we considered various options is the expansion of the definition of midlevel practitioners to include certified registered anesthetists, and clinical nurse specialists as personnel qualified to serve as a LD or TP in PPM laboratories. Currently, this definition is limited to nurse midwives, nurse practitioners, or physician assistants, licensed by the state where the individual practices, if required in the state where the laboratory is located. We considered not expanding this definition or expanding it to include only one of the proposed categories. However, certified registered anesthetists and clinical nurse specialists are both considered advanced practice registered nurses, as are certified nurse midwives and nurse practitioners. All four categories require at least a master's degree in nursing, and all may play a role in providing primary and preventive care services to the public. This may include performing the microscopic examinations required under PPM. As there is no expected cost-increasing impact of adding either of these nursing categories to the midlevel practitioner definition, and the change would increase flexibility and access to PPM testing, we are proposing it in this rule. We are requesting public comments related to alternative changes to be considered to assist us in finalizing this rule.

E. Conclusion

1. CLIA Fees

Although the effect of the changes will increase laboratory costs, implementation of these changes would be negligible in terms of workload for laboratories as these fee increases are operational and technical in nature and do not require additional time to be spent by laboratory employees.

2. Histocompatibility, Personnel, Alternative Sanctions

We estimate that the cost to laboratories, accrediting organizations, and exempt states to comply with the changes proposed in this rule would range between $11,421,708 and $16,983,208 in 2020 dollars for the first year and between $629,200 and $1,635,545 in subsequent years. Although the proposed changes will increase laboratory costs, implementation of these changes, if finalized, streamline and simplify

[20] 83 FR 67723, December 31, 2018 (*https://www.govinfo.gov/content/pkg/FR-2018-12-31/pdf/2018-28359.pdf*).

regulations, add flexibility in laboratory hiring practices, ensure that the LD is on-site at least twice per year, and align histocompatibility testing with current methods and practices. These changes will also allow alternative sanctions to be imposed on CoW laboratories.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 6, 2022.

Rochelle P. Walensky, MD, MPH, Director of the Centers for Disease Control and Prevention, approved this document on July 1, 2022.

List of Subjects in 42 CFR Part 493

Administrative practice and procedure, Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 493—LABORATORY REQUIREMENTS

■ 1. The authority citation for part 493 continues to read as follows:

Authority: 42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16).

■ 2. Amend § 493.2 by—

■ a. Adding the definitions of ''Continuing education (CE) credit hours'', ''Doctoral degree'', ''Experience directing or supervising'', and ''Laboratory training or experience'' in alphabetical order;

■ b. Revising the definition of ''Midlevel practitioner''; and

■ c. Adding the definitions of ''Replacement certificate'' and ''Revised certificate'' in alphabetical order.

The additions and revision read as follows:

§ 493.2 Definitions.

* * * * *

Continuing education (CE) credit hours means either continuing medical education (CME) or continuing education units (CEUs). The CE credit hours must cover the applicable laboratory director responsibilities and be obtained prior to qualifying as a laboratory director.

* * * * *

Doctoral degree means an earned post-baccalaureate degree with at least three years of graduate level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. For purposes of this part, doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatry, doctors of veterinary medicine (DVM) degrees, or honorary degrees.

* * * * *

Experience directing or supervising means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).

* * * * *

Laboratory training or experience means that the training or experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).

Midlevel practitioner means a nurse midwife, nurse practitioner, nurse anesthetist, clinical nurse specialist, or physician assistant licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

* * * * *

Replacement certificate means an active CLIA certificate that is reissued with no changes made.

* * * * *

Revised certificate means an active CLIA certificate that is reissued with changes to one or more fields displayed on the certificate, such as the laboratory's name, address, laboratory director, or approved specialties/subspecialties. For purposes of this part, revised certificates do not include the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service.

* * * * *

§ 493.557 [Amended]

■ 3. Amend § 493.557 in paragraph (b)(4) by removing the reference ''§§ 493.645(a) and 493.646(b)'' and adding in its place the reference ''§§ 493.649(a) and 493.655(b)''.

§ 493.575 [Amended]

■ 4. Amend § 493.575 in paragraph (i) by removing the reference ''§§ 493.645(a) and 493.646(b)'' and adding in its place the reference ''§§ 493.649(a) and 493.655(b)''.

■ 5. Section 493.638 is revised to read as follows:

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee that covers the costs incurred for the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service, and other direct administrative costs, as applicable. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates, the fee is a flat fee that includes the costs for issuing the certificates, collecting the fees, and evaluating whether the procedures, tests, or examinations listed on the application fall within the testing allowed for the requested certificate.

(2) For a certificate of waiver, the fee includes the costs for issuing the certificate; collecting the fees; evaluating whether the procedures, tests, or examinations listed on the application fall within the testing appropriate for the requested certificate; and determining whether a laboratory test meets the criteria for a waived test.

(3) For a certificate for PPM procedures, the fee includes the costs for issuing the certificate, collecting the fees; and evaluating whether the procedures, tests, or examinations listed on the application meet the criteria for inclusion in the subcategory of PPM procedures.

(4) For a certificate of accreditation, the fee includes the costs for issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and evaluating whether the procedures, tests, or examinations listed on the application fall within the testing appropriate for the requested certificate.

(5) For a certificate of compliance, the fee includes the costs for issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, and evaluating whether the procedures, tests or examinations listed on the application fall within the testing appropriate for the requested certificate.

(b) *Fee amount.* (1) The certificate fee amount is set biennially by HHS. CMS will publish a notice in the **Federal Register** biennially with any adjustments to the fee amounts, including any adjustments due to inflation, in accordance with § 493.680. For certificates of waiver and certificates of PPM, the certificate fee amount is based on the category of test complexity performed by the laboratory. For all other certificate types, the fee amount is based on the category of test complexity performed by the laboratory and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, or proficiency testing purposes) and specialties tested, with

the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in paragraph (c) of this section.

(2) Certificate fees are assessed and payable at least biennially.

(3) The amount of the fee payable by the laboratory is the amount listed in the most recent notice published in the **Federal Register** at the time the application, renewal, change in certificate type, or reinstatement is processed by HHS or its designee.

(4) After processing an application for an issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service, HHS or its designee notifies the laboratory of the applicable fee amount.

(c) *Classification of laboratories for purposes of determining the fee amount for certificate types other than certificates of waiver or certificates of PPM.* (1) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assessment, and proficiency testing are excluded from the laboratory's total annual volume.) Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(2) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

(A) Bacteriology.

(B) Mycobacteriology.

(C) Mycology.

(D) Parasitology.

(E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

(A) Syphilis Serology.

(B) General immunology.

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

(A) Routine chemistry.

(B) Endocrinology.

(C) Toxicology.

(D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:

(A) ABO grouping and Rh typing.

(B) Unexpected antibody detection.

(C) Compatibility testing.

(D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

(A) Cytology.

(B) Histopathology.

(C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of Histocompatibility.

(ix) The specialty of Clinical Cytogenetics.

(3) There are 11 schedules of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the 11 schedules in paragraphs (c)(3)(i) through (xi) of this section based on the laboratory's scope and volume of testing:

(i) *Schedule V.* The laboratory performs not more than 2,000 laboratory tests annually.

(ii) *Schedule A.* The laboratory performs tests in no more than three specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(iii) *Schedule B.* The laboratory performs tests in at least four specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iv) *Schedule C.* The laboratory performs tests in no more three specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule D.* The laboratory performs tests in at least four specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(vi) *Schedule E.* The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vii) *Schedule F.* The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(viii) *Schedule G.* The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(ix) *Schedule H.* The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(x) *Schedule I.* The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(xi) *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

■ 6. Section 493.639 is revised to read as follows:

§ 493.639 Fees for revised and replacement certificates.

(a) If, after a laboratory is issued a certificate, it requests a revised certificate, the laboratory must pay a fee to cover the cost of issuing a revised certificate. The fee for a revised certificate is based on the cost to issue the revised certificate to the laboratory. The fee must be paid in full before the revised certificate will be issued.

(1) If laboratory services are added to a certificate of compliance, the laboratory must pay an additional fee if required under § 493.643(d)(2).

(2) [Reserved]

(b) If, after a laboratory is issued a certificate, it requests a replacement certificate, the laboratory must pay a fee to cover the cost of issuing a replacement certificate. The fee for a replacement certificate is based on the cost of issuing the replacement certificate to the laboratory. The fee must be paid in full before issuing the replacement certificate.

■ 7. Section 493.643 is revised to read as follows:

§ 493.643 Additional fees applicable to laboratories issued a certificate of compliance.

(a) *Fee requirement.* In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) *Costs included in the fee.* Included in the fee for determining program compliance are costs for evaluating qualifications of laboratory personnel; monitoring laboratory proficiency testing; and conducting onsite inspections of laboratories including: documenting deficiencies, evaluating laboratories' plans to correct deficiencies, creating training programs, training surveyors, and necessary administrative costs.

(c) *Fee amount.* The amount of the fee for determining program compliance is set biennially by HHS.

(1) The fee is based on the category of test complexity and schedules or ranges of annual laboratory test volume and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of determining program compliance as set forth in § 493.638(c).

(2) The fee is assessed and payable biennially.

(3) The amount of the program compliance fee is the amount applicable to the laboratory listed in the most recent notice published in the **Federal Register** at the time that the fee is generated.

(d) *Additional fees.* (1) If a laboratory issued a certificate of compliance has been inspected and follow-up visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the follow-up visits. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed fee.

(2) If, after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(3) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the Government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

(4) Laboratories with a certificate of compliance must pay a fee if the laboratory fails to perform successfully in proficiency testing for one or more specialties, subspecialties, analytes, or tests specified in subpart I of this part, and it is necessary to conduct a desk review of the unsuccessful performance. The additional fee is based on the actual resources and time necessary to perform the desk review. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

■ 8. Amend § 493.645—

■ a. By revising the section heading;

■ b. By removing paragraph (a);

■ c. By redesignating paragraphs (b) and (c) as paragraphs (a) and (b);

■ d. By revising newly redesignated paragraph (a); and

■ e. In newly redesignated paragraph (b) by adding a paragraph heading.

The revisions and addition read as follows:

§ 493.645 Additional fees applicable to laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) *Accredited laboratories.* (1) A laboratory that is issued a certificate of accreditation is assessed an additional fee to cover the cost of performing validation inspections described at § 493.563. All accredited laboratories share in the cost of these inspections. These costs are five percent of the same costs as those that are incurred when inspecting nonaccredited laboratories of the same schedule (or range) and are paid biennially by each accredited laboratory whether the accredited laboratory has a validation inspection or not. HHS revokes the laboratory's certificate of accreditation for failure to pay the fee.

(2) If a laboratory issued a certificate of accreditation has been inspected and follow-up visits are necessary because of identified deficiencies, HHS assesses the laboratory an additional fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the follow-up visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the fee.

(b) *Complaint surveys.* * * *

§ 493.646 [Removed]

■ 9. Section 493.646 is removed.

■ 10. Section 493.649 is revised to read as follows:

§ 493.649 Additional fees applicable to approved State laboratory programs.

(a) *Approved State laboratory programs.* State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) The State's pro rata share of general overhead to administer the laboratory certification program under section 353 of the PHS Act.

(b) [Reserved]

■ 11. Section 493.655 is added to read as follows:

§ 493.655 Payment of fees.

(a) Except for laboratories covered by approved State laboratory programs, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For approved State laboratory programs, HHS estimates the cost of conducting validation inspections as described at § 493.563 within the State on at least a biennial period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

■ 12. Section 493.680 is added to read as follows:

§ 493.680 Methodology for determining the biennial fee increase.

(a) *General rule.* Except for fees assessed to State laboratory programs approved by HHS, the fee amounts described in this subpart are subject to a biennial increase based on a two-part calculation of the Consumer Price Index-Urban (CPI–U) inflation adjustment and, if applicable, an additional increase as follows:

(1) CMS calculates the inflation rate using the compounded CPI–U over 2 years and, provided that the calculated rate is greater than zero, applies an increase to all fee amounts equal to the calculated rate.

(2) If the total fee amounts, including any increase applied under paragraph (a)(1) of this section, do not match or exceed actual program obligations based on a review of the previous 2 years' obligations, CMS applies an additional across the board increase to each laboratory's fees by calculating the difference between the total fee amounts and actual program obligations.

(b) *Baseline.* Any increase applied under paragraph (a) of this section is incorporated into the baseline fee amounts for any subsequent biennial increase.

(c) *Publication.* Any increase applied under paragraph (a) of this section, including the calculation thereof, will be published as a notice in the **Federal Register**.

■ 13. Section 493.1278 is amended by—

■ a. Revising paragraphs (a)(1) and (2);

■ b. Removing paragraph (a)(3);

■ c. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(3) and (4), respectively;

■ d. Revising newly redesignated paragraph (a)(3);

■ e. Removing paragraphs (b)(1), (2), and (3);
■ f. Redesignating paragraphs (b)(4) and (5) as paragraphs (b)(1) and (2), respectively;
■ g. In newly redesignated paragraph (b)(1), removing the phrase ''latest report of the'' and the second sentence;
■ h. Revising newly redesignated paragraph (b)(2);
■ i. Removing paragraph (b)(6).
■ j. Revising paragraphs (c), (d), (e), and (f); and
■ k. Removing paragraph (g).

The revisions read as follows:

§ 493.1278 Standard: Histocompatibility.

(a) * * *

(1) Use a continuous monitoring system and alert system to monitor the storage temperature of specimens (donor and recipient) and reagents and notify laboratory personnel when temperature limits are exceeded.

(2) Establish and follow written policies and procedures for the storage and retention of specimens based on the specific type of specimen. All specimens must be easily retrievable. The laboratory must have an emergency plan for alternate storage.

(3) If the laboratory uses immunologic reagents to facilitate or enhance the isolation or identification of lymphocytes or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

* * * * *

(b) * * *

(2) Have available and follow written criteria for determining when antigen and allele typing are required.

(c) *Antibody screening and identification.* The laboratory must make a reasonable effort to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening, identification, and crossmatch.

(d) *Crossmatching.* For each type of crossmatch that a laboratory performs, the laboratory must do the following, as applicable:

(1) Establish and follow written policies and procedures for performing a crossmatch.

(2) Have available and follow written criteria for the following:

(i) Defining donor and recipient human leukocyte antigen (HLA) antigens, alleles, and antibodies to be tested;

(ii) Defining the criteria necessary to assess a recipient's alloantibody status;

(iii) Assessing recipient antibody presence or absence on an ongoing basis;

(iv) Typing the donor at the serologic level to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;

(v) Describing the circumstances in which pre- and post-transplant confirmation testing of donor and recipient specimens is required;

(vi) Making available all applicable donor and recipient test results to the transplant team;

(vii) Ensuring immunologic assessments are based on test results obtained from a test report from a CLIA-certified laboratory; and

(viii) Defining time limits between recipient testing and the performance of a crossmatch.

(3) The test report must specify the type of crossmatch performed.

(e) *Transplantation.* Laboratories performing histocompatibility testing for infusion and transplantation purposes must establish and follow written policies and procedures specifying the histocompatibility testing (that is, HLA typing, antibody screening and identification, and crossmatching) to be performed for each type of cell, tissue, or organ to be infused or transplanted. The laboratory's policies and procedures must include, as applicable—

(1) Testing protocols that address:

(i) Transplant type (organ, tissue, cell);

(ii) Donor (living, deceased, or paired); and

(iii) Recipient (high risk vs. unsensitized);

(2) Type and frequency of testing required to support clinical transplant protocols; and

(3) Process to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of the transplant. If the laboratory is unable to obtain a recipient specimen on the day of the transplant, the laboratory must have a process to document its efforts to obtain the specimen.

(f) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

■ 14. Amend § 493.1359:
■ a. In paragraph (a) by removing the word ''and'';
■ b. By revising paragraph (b)(2); and
■ c. By adding paragraphs (c) and (d).

The revision and additions read as follows:

§ 493.1359 Standard; PPM laboratory director responsibilities.

* * * * *

(b) * * *

(2) Is performed in accordance with applicable requirements in this subpart and subparts H, J, and K of this part;

(c) Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(1) Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing;

(2) Monitoring the recording and reporting of test results;

(3) Review of test results or worksheets;

(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and

(5) Assessment of problem solving skills; and

(d) Evaluating and documenting the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.

■ 15. Amend § 493.1405 by revising paragraph (b) to read as follows:

§ 493.1405 Standard; Laboratory director qualifications.

* * * * *

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least 1 year directing or supervising nonwaived laboratory testing; and

(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; or

(3)(i) Hold an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet master's equivalency; and

(B) Have at least 16 semester hours of additional doctoral level coursework in biology, chemistry, medical technology (MT), or clinical laboratory science (CLS); or

(C) A thesis or research project in biology/chemistry/MT/CLS related to

laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(iii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; and

(A) Be certified and continue to be certified by a board approved by HHS; and

(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or

(4)(i) Have earned a master's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet bachelor's degree equivalency; and

(B) Have at least 16 semester hours of additional graduate-level coursework in biology, chemistry, medical technology, or clinical laboratory science; or

(iii)(A) Meet bachelor's degree equivalency; and

(B) Have at least 16 semester hours, which may include a combination of graduate-level coursework in biology, chemistry, medical technology, or clinical laboratory science and a thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(iv) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and

(v) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and

(vi) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407; or

(5)(i) Have earned a bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(A) 48 semester hours of medical laboratory technology courses; or

(B) 48 semester hours of science courses that include—

(*1*) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(*2*) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(*3*) 24 semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(iii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and

(iv) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and

(v) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407.

(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

§ 493.1406 [Removed]

■ 16. Section 493.1406 is removed.

■ 17. Amend § 493.1407 by revising paragraph (c) to read as follows:

§ 493.1407 Standard; Laboratory director responsibilities.

* * * * *

(c) The laboratory director must:

(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

* * * * *

■ 18. Amend § 493.1411 by revising paragraph (b) to read as follows:

§ 493.1411 Standard; Technical consultant qualifications.

* * * * *

(b) The technical consultant must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(3)(i) Hold an earned doctoral or master's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet either requirements in § 493.1405(b)(3)(ii) or (b)(4)(ii) or (iii); and

(iii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4)(i) Have earned a bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet § 493.1405(b)(5)(ii); and

(iii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(5)(i) Have earned an associate's degree in medical laboratory technology or clinical laboratory science; and

(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

(6) For blood gas analysis, the individual must—

(i) Be qualified under paragraph (b)(1), (2), (3), or (4) of this section; or

(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or

(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

Note 1 to paragraph (b): The technical consultant requirements for ''laboratory training or experience, or both'' in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service,

excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

■ 19. Amend § 493.1423 by revising paragraph (b) to read as follows:

§ 493.1423 Standard; Testing personnel qualifications.

* * * * *

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or

(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology, or nursing from an accredited institution; or

(3) Meet the requirements in § 493.1405(b)(3)(ii), (b)(4)(ii) and (iii), or (b)(5)(ii); or

(4) Have earned an associate's degree in a chemical, biological science or medical laboratory technology or nursing from an accredited institution; or

(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(6)(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

(7) For blood gas analysis, the individual must—

(i) Be qualified under paragraph (b)(1), (2), (3), or (4) of this section; or

(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis; or

(C)(*1*) Have earned an associate's degree related to pulmonary function from an accredited institution; and

(*2*) Have at least 2 years of training or experience, or both, in blood gas analysis.

■ 20. Amend § 493.1443 by revising paragraph (b) to read as follows:

§ 493.1443 Standard: Laboratory director qualifications.

* * * * *

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(i) Have at least 2 years of experience directing or supervising high complexity testing; and

(ii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or

(3)(i) Hold an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet master's equivalency; and

(B) Have at least 16 semester hours of additional doctoral level coursework in biology, chemistry, medical technology, or clinical laboratory science; or

(C) A thesis or research project in biology, chemistry, medical technology, or clinical laboratory science related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(iii) Be certified and continue to be certified by a board approved by HHS; and

(iv) Have at least 2 years of:

(A) Laboratory training or experience, or both: and

(B) Laboratory experience directing or supervising high complexity testing; and

(v) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or

(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

■ 21. Amend § 493.1445 by revising paragraph (c) to read as follows:

§ 493.1445 Standard; Laboratory director responsibilities.

* * * * *

(c) The laboratory director must:

(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

* * * * *

■ 22. Section 493.1449 is revised to read as follows:

§ 493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the

State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—

(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or

(3)(i) Have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet the requirements in § 493.1443(b)(3)(ii); and

(B) [Reserved]

(iii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or

(4)(i) Have earned a master's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet bachelor's degree equivalency; and

(B) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, or clinical laboratory science or medical technology; or

(iii)(A) Meet bachelor's degree equivalency; and

(B) Have at least 16 semester hours, which may include a combination of graduate level coursework in biology, chemistry, medical technology, or clinical laboratory science and a thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(iv) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or

(5)(i) Have earned a bachelor's degree in a chemical or biological science or clinical laboratory science or medical technology from an accredited institution; or

(ii) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(A) 48 semester hours of medical laboratory technology courses; or

(B) 48 semester hours of science courses that include—

(*1*) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(*2*) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(*3*) 24 semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(iii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty.

(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or

(3)(i) Have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet the education requirement at § 493.1443(b)(3)(ii); and

(iii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or

(4)(i) Have earned a master's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet the education requirement at paragraphs (c)(4)(ii) and (iii) of this section; and

(iii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or

(5)(i) Have earned a bachelor's degree in a chemical or biological science or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet the education requirement at paragraph (c)(5)(ii) of this section; and

(iii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

(e)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(2) An individual qualified under paragraph (b) or (d)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (k)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains

ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(1) Meet one of the following requirements:

(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) An individual qualified under paragraph (b) or (f)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(2) For tests in dermatopathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Meet one of the following requirements:

(*1*) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(*2*) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or

(*3*) Be certified in dermatology by the American Board of Dermatology; or

(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(3) For tests in ophthalmic pathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Must meet one of the following requirements:

(*1*) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(*2*) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B)(*2*) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Be certified in oral pathology by the American Board of Oral Pathology; or

(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(h) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(*i*) Have an earned doctoral degree in a biological or clinical laboratory science or medical technology from an accredited institution; or

(*ii*) Meet the education requirement at § 493.1443(b)(3)(ii); and

(iii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

Note 1 to paragraph (h): The technical supervisor requirements for ''laboratory training or experience, or both'' in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

(i) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science or medical technology from an accredited institution;

(ii) Meet the education requirement at § 493.1443(b)(3)(ii); and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

■ 23. Amend § 493.1461 by revising paragraphs (c), (d)(3)(i), and (e)(1) and (4) to read as follows:

§ 493.1461 Standard: General supervisor qualifications.

* * * * *

(c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical,

biological, or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2)(i) Qualify as testing personnel under § 493.1489(b)(3); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(3) Meet the requirements at § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or

(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

(d) * * *

(3)(i) Have earned an associate's degree related to pulmonary function from an accredited institution; and

* * * * *

(e) * * *

(1) In histopathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (f)(1);

* * * * *

(4) In oral pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (g).

§ 493.1462 [Removed]

■ 24. Section 493.1462 is removed.

■ 25. Amend § 493.1463 by revising paragraph (b)(4) to read as follows:

§ 493.1463 Standard: General supervisor responsibilities.

* * * * *

(b) * * *

(4) Evaluating and documenting the competency of all testing personnel.

* * * * *

■ 26. Amend § 493.1483 by revising paragraph (b) to read as follows:

§ 493.1483 Standard: Cytotechnologist qualifications.

* * * * *

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Notwithstanding any other provision of this section, an individual is considered qualified as a cytotechnologist under this section if they were qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

■ 27. Amend § 493.1489 by revising paragraph (b) to read as follows:

§ 493.1489 Standard; Testing personnel qualifications.

* * * * *

(b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or

(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology or nursing from an accredited institution;

(ii) Be qualified under the requirements of § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or

(3)(i) Have earned an associate's degree in a laboratory science or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(*1*) 24 semester hours of medical laboratory technology courses; or

(*2*) 24 semester hours of science courses that include—

(*i*) 6 semester hours of chemistry;

(*ii*) 6 semester hours of biology; and

(*iii*) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes:

(*1*) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or

(*2*) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or

(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

(6) For blood gas analysis—

(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section;

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate's degree related to pulmonary function from an accredited institution; or

(7) For histopathology, meet the qualifications of § 493.1449(b) or (l) to perform tissue examinations.

§ 493.1491 [Removed]

■ 28. Section 493.1491 is removed.

■ 29. Amend § 493.1804 by revising paragraph (c)(1) to read as follows:

§ 493.1804 General considerations.

* * * * *

(c) * * *

(1) CMS may impose alternative sanctions in lieu of, or in addition to, principal sanctions.

* * * * *

Dated: July 13, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–15300 Filed 7–22–22; 4:15 pm]

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Part V

Department of Transportation

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, et al.

Hazardous Materials: Harmonization With International Standards; Final Rule

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, 175, 176, 178, and 180

[Docket No. PHMSA–2019–0030 (HM–215P)]

RIN 2137–AF46

Hazardous Materials: Harmonization With International Standards

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: PHMSA is amending the Hazardous Materials Regulations (HMR) to maintain alignment with international regulations and standards by adopting various amendments, including changes to proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, air transport quantity limitations, and vessel stowage requirements. Additionally, PHMSA is amending the HMR to allow for better alignment with Transport Canada's Transportation of Dangerous Goods Regulations. PHMSA is also withdrawing the unpublished October 1, 2020, Notice of Enforcement Policy Regarding International Standards on use of select updated international standards in complying with the HMR during the pendency of this rulemaking.

DATES:

Effective date: This rule is effective August 25, 2022.

Voluntary compliance date: January 1, 2021.

Delayed compliance date: July 26, 2023.

Incorporation by reference date: The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register on August 25, 2022. The incorporation by reference of certain other publications listed in this rule was approved by the Director of the Federal Register as of May 11, 2020.

FOR FURTHER INFORMATION CONTACT: Candace Casey, Standards and Rulemaking, Steven Andrews, Standards and Rulemaking, or Aaron Wiener, International Program, at (202) 366–8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, East Building, 2nd Floor, Washington, DC 20590–0001.

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I. Executive Summary

As discussed in further detail in this final rule (*see* the V. Section-by-Section Review of Amendments), the Pipeline and Hazardous Materials Safety Administration (PHMSA) amends certain sections of the Hazardous Materials Regulations (HMR; 49 CFR parts 171 to 180) to maintain alignment with international regulations and standards by adopting various amendments, including changes to proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, air transport quantity limitations, and vessel stowage requirements. Furthermore, this final rule addresses the 17 sets of comments received in response to the Notice of Proposed Rulemaking (NPRM) [1] published in August 2021. Overall, the comments to the NPRM were generally supportive of the proposals made; however, PHMSA did receive a few comments seeking further clarification or revisions to the NPRM which PHMSA also addresses in this final rule.

PHMSA expects that the adoption of the regulatory amendments in this final rule will facilitate transportation efficiency while maintaining the high safety standard currently achieved under the HMR. For example, the final rule will improve the safe transportation of vaccines and other medical materials associated with the ongoing response to the coronavirus disease 2019 (COVID–19) public health emergency, or any similar public health emergency that may emerge, by removing unnecessary regulatory hurdles to the international movement of those materials. This final rule will also align HMR requirements with anticipated increases in the volume of lithium batteries transported in interstate commerce from electrification of the transportation and other economic sectors. PHMSA also notes that the harmonization of the HMR with international consensus standards could reduce delays and interruptions of hazardous materials during transportation. The amendments may also lower greenhouse gas (GHG) emissions and safety risks to minority, low-income, underserved, and other disadvantaged populations, and communities in the vicinity of interim storage sites and transportation arteries and hubs.

The following list summarizes the more noteworthy amendments set forth in this final rule:

- *Incorporation by Reference:* PHMSA is incorporating by reference updated versions of the following international hazardous materials regulations and standards: the 2021–2022 Edition of the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions); Amendment 40–20 to the International Maritime Dangerous Goods Code (IMDG Code); the 21st revised edition of the United Nations Recommendations on the Transport of Dangerous Goods—Model Regulations (UN Model Regulations); and the International Atomic Energy Agency (IAEA) ''Specific Safety Requirements Number SSR–6: Regulations for the Safe Transport of Radioactive Material 2018 Edition'' (SSR–6, Rev.1). PHMSA also incorporates by reference several new or updated International Organization for Standardization (ISO) standards, as well as an updated version of the Organization for Economic Cooperation and Development (OECD) Guidelines for the Testing of Chemicals *Test No. 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method.*
- *Transport Canada temporary certificates:* PHMSA is amending the HMR to authorize the highway or rail transportation of a hazardous material within the United States pursuant to a temporary certificate issued under Transport Canada's Transportation of Dangerous Goods Regulations (TDG Regulations).
- *Hazardous Materials Table:* PHMSA is amending the Hazardous Materials Table (HMT; 49 CFR 172.101) to add, revise, or remove certain proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, bulk packaging

[1] 86 FR 43844 (Aug. 10, 2021).

requirements, and passenger and cargo aircraft maximum quantity limits.

• *Data loggers:* PHMSA is adopting provisions for lithium batteries in equipment that are attached to or contained in packagings, large packagings, intermediate bulk containers (IBCs), or cargo transport units as equipment in use or intended for use during transport, such as data loggers. Additionally, in response to the COVID–19 public health emergency and consistent with revisions to the 2021–2022 ICAO Technical Instructions, PHMSA is adding provisions specific to the air transportation of these items used in association with shipments of COVID–19 pharmaceuticals, including vaccines.

• *Removal of metal wall thickness requirements for certain metal IBCs:* PHMSA is removing the minimum wall thickness requirements for metal IBCs that have a capacity of 1500 liters (L) or less.

• *Stabilized fish meal or fish scrap by air:* PHMSA is authorizing the transport of stabilized fish meal or fish scrap (UN2216) on passenger and cargo aircraft. Currently, when transported as a Class 9 material, stabilized fish meal or fish scrap is only authorized for transportation by vessel. As a part of this amendment, PHMSA is also expanding the applicability of the stabilization requirements currently in place for shipments of these materials by vessel.

• *UN3549 Category A Medical Wastes:* PHMSA is adding an entry to the HMT for ''UN3549, Medical Waste, Category A, Affecting Humans, *solid* or Medical Waste, Category A, Affecting Animals *only, solid.*'' This entry provides an additional shipping description for solid materials meeting the Category A classification criteria that are not appropriate for classification in existing entries/classes ''UN2814, Infectious substances, affecting humans, 6.2'' or ''UN2900, Infectious substances, affecting animals *only,* 6.2.'' Solid medical waste containing Category A infectious substances generated from the medical treatment of humans or veterinary treatment of animals (*e.g.,* disposable personal protective equipment) may be assigned to UN3549. Although PHMSA is not adopting certain packaging provisions adopted in the UN Model Regulations (UNMR), we are assigning Special Provision 131—which directs shippers to request approval from the Associate Administrator, through a special permit, prior to transportation—to UN3549. Additionally, PHMSA is amending certain parts of § 173.134, which provides definitions and exceptions for Class 6, Division 6.2 hazardous materials, to include references to this new UN number and proper shipping name.

• *Additional packagings for ''UN2211, Polymeric beads, expandable, evolving flammable vapor'' and ''UN3314, Plastic molding compound in dough, sheet or extruded rope form evolving flammable vapor'':* PHMSA is expanding the authorized packagings for polymeric beads and plastic molding compound to include combination packagings rather than limiting packaging options to single packagings.

• *Miscellaneous revisions of requirements pertaining to the transportation of lithium batteries:* PHMSA is amending several provisions, including, but not limited to, minimum size markings and modification of stowage requirements for lithium batteries including those offered as damaged/defective or for disposal/recycling. PHMSA expects the revisions will contribute to the safe transportation of increased volumes of lithium batteries anticipated as a result of the increased use of that technology in the transportation and other economic sectors.

• *Definition of SADT (Self-accelerating decomposition temperature) and SAPT (Self-accelerating polymerizing temperature):* PHMSA is amending the definitions of SADT and SAPT to clarify that the lowest temperature at which these chemical reactions may occur in a packaging, IBC, or portable tank.

• *Periodic inspection for chemicals under pressure:* PHMSA is extending the periodic inspection, from five to ten years, for cylinders that are filled with hazardous materials described as ''UN3500, Chemicals under pressure, n.o.s.'' that are also used as fire extinguishing agents.

• *Technical name requirements for marine pollutants:* PHMSA is amending provisions pertaining to the addition of technical names to the shipping description when transporting hazardous materials that contain marine pollutants. These amendments aim to provide flexibility regarding documentation and marking requirements, which currently require identifying the technical names of marine pollutant components in those materials. Additionally, PHMSA is amending §§ 172.203(l) and 172.322 to limit the applicability of requirements for specific marine pollutant constituents for generic entries (indicated by the letter ''G'' in column 1 of the Hazardous Materials Table) and those containing ''n.o.s.'' as part of the proper shipping names.

• *Stability tests for nitrocellulose:* PHMSA is adding stability testing requirements for nitrocellulose to require that these materials meet the criteria of the Bergmann-Junk test or methyl violet paper test in the UN Manual of Tests and Criteria, Appendix 10.

Some of the amendments represent clear improvements in safety, such as nitrocellulose stability testing, additional closures for packagings intended for pyrophoric materials, and on deck stowage requirements for lithium batteries transported by vessel for disposal, recycling, or those that are damaged or defective. Furthermore, all of the amendments are expected to maintain the HMR's high safety standard for the public and the environment. Additionally, PHMSA anticipates that there are safety benefits to be derived from improved compliance related to consistency amongst domestic and international regulations.

Finally, as further explained in the Regulatory Impact Analysis (RIA), PHMSA calculates that the aggregate benefits of the amendments in this final rule more than justify their aggregate costs. In fact, PHMSA estimates that the annualized quantified net cost savings of this rulemaking, using a 7 percent discount rate, are approximately $24.5 to $28.3 million per year.

II. Background

The Federal hazardous materials transportation law (49 U.S.C. 5101 *et seq.*) directs PHMSA to participate in relevant international standard-setting bodies and encourages alignment of the HMR with international transport standards consistent with the promotion of safety and the public interest. *See* 49 U.S.C. 5120. This statutory mandate reflects the importance of international standard-setting activity considering the globalization of commercial transportation of hazardous materials. Harmonization of the HMR with those efforts can reduce the costs and other burdens of complying with multiple or inconsistent safety requirements between nations. Consistency between the HMR and current international standards can also enhance safety by: (1) ensuring that the HMR is informed by the latest best practices and lessons learned; (2) improving the understanding of—and compliance with—pertinent requirements; (3) facilitating the smooth flow of hazardous materials from their points of origin to their points of destination, thereby avoiding risks to the public and the environment from release of hazardous materials from delays or

interruptions in the transportation of those materials; and (4) enabling consistent emergency response procedures in the event of a hazardous materials incident.

PHMSA participates in the development of international regulations and standards for the transportation of hazardous materials. It also adopts within the HMR international standards consistent with PHMSA's safety mission. PHMSA reviews and evaluates each international standard it considers for incorporation within the HMR on its own merits, to include the effects on transportation safety, the environmental impacts, and any economic impacts. PHMSA's goal is to harmonize with international standards without diminishing the level of safety currently provided by the HMR or imposing undue burdens on the regulated community.

In a final rule published December 21, 1990,[2] PHMSA's predecessor—the Research and Special Programs Administration (RSPA)—comprehensively revised the HMR for greater consistency with the UNMR. The UNMR constitute a set of recommendations issued by the United Nations Committee of Experts (UNSCOE) on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The UNMR are amended and updated biennially by the UNSCOE and serve as the basis for national, regional, and international modal regulations, including the ICAO Technical Instructions and IMDG Code.

PHMSA has evaluated recent updates to the international standards and is revising the HMR to adopt changes consistent with revisions to the 2021–2022 Edition of the ICAO Technical Instructions, Amendment 40–20 to the IMDG Code,[3] and the 21st revised edition of the UNMR, all of which were published by or in effect on January 1, 2021. PHMSA issued a Notice of Enforcement Policy Regarding International Standards[4] on October 1, 2020, stating that while PHMSA is considering the 2021–2022 Edition of the ICAO Technical Instructions and Amendment 40–20 to the IMDG Code for potential adoption into the HMR, PHMSA and other Federal agencies that enforce the HMR—*e.g.,* the Federal Railroad Administration, the Federal Aviation Administration (FAA), the Federal Motor Carrier Safety Administration, and the United States Coast Guard—will not take enforcement action against any offeror or carrier who uses these standards as an alternative to complying with current HMR requirements when all or part of the transportation is by air with respect to the ICAO Technical Instructions, or by vessel with respect to the IMDG Code. In addition, that Notice stated PHMSA, and its modal partners will not take enforcement action against any offeror or carrier who offers or accepts for domestic or international transportation by any mode packages marked or labeled in accordance with these standards. PHMSA withdraws its October 1, 2020, Notice of Enforcement Policy Regarding International Standards as of the effective date of this final rule. Additionally, in response to the ongoing global COVID–19 public health emergency, on December 31, 2020, and February 23, 2021, ICAO published addenda to the 2021–2022 Edition of the ICAO Technical Instructions to provide additional provisions and exceptions to reduce regulatory compliance burdens for the transport of certain hazardous materials, such as alcohols and aerosols used for hygienic purposes, by air. PHMSA is including those changes to international standards in this final rule. Finally, PHMSA is incorporating by reference these new international regulations and standards as well as new requirements from the IAEA, ''Specific Safety Requirements Number SSR–6: Regulations for the Safe Transport of Radioactive Material 2018 Edition'' (SSR–6, Rev.1); several new or updated ISO standards; and an updated version of the OECD Guidelines for the Testing of Chemicals *Test No. 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method.* The standards incorporated by reference are authorized for use for domestic transportation, under specific conditions, by part 171, subpart C of the HMR.

During PHMSA's development of the final rule, the President issued a series of Executive Orders coordinating the Federal response to the COVID–19 public health emergency—a handful of those are pertinent to this final rule. Specifically, section 2 of Executive Order 13987 (''Organizing and Mobilizing the United States Government to Provide a Unified and Effective Response to Combat COVID–19 and To Provide United States Leadership on Global Health and Security'')[5] contemplates broad-based action across the Federal Government to ''produce, supply, and distribute personal protective equipment, vaccines, tests, and other supplies for the Nation's COVID–19 response.'' Similarly, Executive Order 14002 (''Economic Relief Related to COVID–19 Pandemic'')[6] directs Federal agencies like PHMSA to respond to the economic harm caused by the COVID–19 public health emergency by promptly identifying actions they can take within existing authorities to provide economic relief to affected persons and businesses. Lastly, the President has announced ambitious reductions in national GHG emissions to combat climate change, identifying electrification of the transportation and other economic sectors—to include enabling more widespread use of electric storage technologies, such as lithium batteries—as a critical element of that effort.[7]

III. Incorporation by Reference Discussion Under 1 CFR Part 51

According to the Office of Management and Budget (OMB), Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,'' government agencies must use voluntary consensus standards wherever practical in the development of regulations.

PHMSA currently incorporates by reference into the HMR all or parts of several standards and specifications developed and published by standard development organizations (SDOs). In general, SDOs update and revise their published standards every two to five years to reflect modern technology and best technical practices. The National Technology Transfer and Advancement Act of 1995 (NTTAA; Pub. L. 104–113) directs Federal agencies to use standards developed by voluntary consensus standards bodies in lieu of government-written standards whenever possible. Voluntary consensus standards

[2] 55 FR 52401 (Dec. 21, 1990).

[3] Amendment 40–20 to the IMDG Code may be voluntarily complied with as of January 1, 2021; however, Amendment 39–18 will remain effective through May 31, 2022.

[4] PHMSA, Notice of Enforcement Policy Regarding International Standards (Oct. 1, 2020), *https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-10/Notice%20of%20Enforcement%20Policy%20Regarding%20International%20Standards%20Oct%201%202020.pdf.*

[5] 86 FR 7019 (Jan. 20, 2021).

[6] 86 FR 7229 (Jan. 21, 2021).

[7] See, *e.g.,* White House, ''Fact Sheet: President Biden Sets 2030 Greenhouse Gas Pollution Reduction Target Aimed at Creating Good-Paying Union Jobs and Securing U.S. Leadership on Clean Energy Technologies'' (Apr. 21, 2021), *https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/22/fact-sheet-president-biden-sets-2030-greenhouse-gas-pollution-reduction-target-aimed-at-creating-good-paying-union-jobs-and-securing-u-s-leadership-on-clean-energy-technologies/.*

bodies develop, establish, or coordinate technical standards using agreed-upon procedures. OMB issued Circular A–119 to implement section 12(d) of the NTTAA relative to the utilization of consensus technical standards by Federal agencies. This circular provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. Accordingly, PHMSA is responsible for determining which currently referenced standards should be updated, revised, or removed, and which standards should be added to the HMR. Revisions to materials incorporated by reference in the HMR are handled via the rulemaking process, which allows for the public and regulated entities to provide input.

The UNMR, the UN Manual of Tests and Criteria, the IAEA Regulations for the Safe Transport of Radioactive Material, and the OECD Guidelines for the Testing of Chemicals *Test No. 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method* are free and easily accessible to the public on the internet, with access provided through the parent organization websites. The ICAO Technical Instructions, IMDG Code, and all ISO standard references are available for interested parties to purchase in either print or electronic versions through the parent organization websites. The price charged for those standards not freely available helps to cover the cost of developing, maintaining, hosting, and accessing these standards. The specific standards are discussed in greater detail in ''V. Section-by-Section Review of Amendments Section'' of this document.

IV. Comment Discussion

In response to the NPRM, PHMSA received 17 sets of comments [8] from the following persons:

- Airbus
- Amazon
- Anonymous
- Council on the Safe Transportation of Hazardous Articles (COSTHA)
- Dangerous Goods Advisory Council (DGAC)
- Dow Chemical Company (Dow)
- Elanore Tessitore
- Healthcare Waste Institute (HWI)
- Institute for the Makers of Explosives (IME)
- Luxfer Canada
- Luxfer Gas Cylinders
- Medical Device Transport Council (MDTC)
- The Rechargeable Battery Association (PRBA)
- Reggie Valentine
- Rigid Intermediate Bulk Container Association (RIBCA)
- Reusable Industrial Packaging Association (RIPA)
- Stericycle

PHMSA received comments from Amazon, DGAC, COSTHA, MDTC, and PRBA, all providing general support for harmonization with international standards with additional support from Luxfer Gas Cylinders for the incorporation by reference of the ISO standards applicable to cylinders. In addition, PHMSA received a comment from IME encouraging expeditious adoption of changes to international regulations into the HMR.

Comments concerning the sunset provisions for polymerizing substances, damaged or defective batteries, and comments outside the scope of this rulemaking are discussed below. All other comments specific to proposed changes to HMR sections are addressed in the ''V. Section-by-Section Review of Amendments'' of this document.

A. Comments Outside the Scope of This Rulemaking

PHMSA received a comment from an anonymous person noting that PHMSA did not propose to update the publications referenced in § 173.58(c). This section addresses the assignment of Class and Divisions for new explosives and paragraph (c) specifically addresses classification of Division 1.6 explosives. The anonymous commenter states the provisions of § 173.58(c) are outdated relative to the 21st revised edition of the UNMR and the UN Manual of Tests and Criteria 7th revised edition. The anonymous commenter suggests that PHMSA review and amend § 173.58(c) to maintain alignment with international regulations. Specifically, the commenter notes that the UN provisions (as outlined in the UN Manual of Test and Criteria) currently specify that explosive substances in Division 1.6 articles must be ''predominantly containing an extremely insensitive substance'' and must no longer be ''exclusively containing an extremely insensitive substance'' as currently cited in § 173.58(c). Additionally, the commenter adds that a Division 1.6 article fragment impact test has been added to the UN provisions (as outlined in the UN Manual of Test and Criteria) for Division 1.6 articles and that test is not cited within § 173.58(c).

PHMSA acknowledges the commenter's concerns over the testing requirements for Division 1.6 explosives in § 173.58(c). However, PHMSA did not propose changes to this section in the NPRM and, therefore, declines to make such revisions in this final rule without further evaluation by PHMSA subject matter experts and an opportunity for stakeholders to comment on the issue. If the commenter has a proposal to revise the regulatory text § 173.58(c), PHMSA encourages the commenter to submit a petition for rulemaking in accordance with 49 CFR 106.100 and provide specific justification that the regulatory text at § 173.58(c) must be updated to mirror language in the updated industry standards referenced elsewhere in § 173.58.

In its comments on the NPRM, MDTC noted that PHMSA did not address the inclusion of Special Provision A201—approval of the State of Origin and the operator—and other provisions codified in the HM–224I Interim Final Rule (IFR).[9] While PHMSA appreciates the comments from MDTC, we are not addressing comments to the HM–224I IFR in this final rule. PHMSA will address and respond to all comments on the HM–224I IFR in a future HM–224I final rule.

B. Polymerizing Substances

Dow and DGAC provided comments on the sunset dates for polymerizing substances as outlined in a previously issued international harmonization final rule, HM–215O.[10] In HM–215O, PHMSA extended the sunset dates to January 2, 2023, for polymerizing substances to allow PHMSA to complete an ongoing research project and analyze all comments and data concerning the issue submitted to the docket for the HM–215O [11] NPRM. Dow and DGAC are concerned that the next international harmonization rule will be published after January 2, 2023, resulting in polymerizing substances regulations no longer being in effect for transportation in accordance with the HMR. PHMSA expects to address these concerns regarding sunset dates for transportation of polymerizing substances in a final rule prior to the expiration of the sunset dates.

C. Guidance on Damaged or Defective Batteries

In its comments, MDTC and PRBA requested that PHMSA include a note from Special Provision 376 of the UNMR for determining whether a lithium battery is damaged or defective within the amendments adopted in this

[8] *https://www.regulations.gov/docket/PHMSA-2019-0030/comments.*

[9] 84 FR 8006 (Mar. 6, 2019).

[10] 79 FR 46012 (Aug. 16, 2014).

[11] 85 FR 27810 (May 11, 2020).

final rule. The commenters state this note will better assist shippers on how to evaluate whether a lithium battery is considered damaged or defective. PHMSA appreciates MDTC and PRBA bringing this issue to our attention and concurs that more guidance is needed to help in the determination of when a lithium battery is considered damaged or defective. However, the note to Special Provision 376 of the UNMR is guidance and not prescriptive language within that international standard. While PHMSA does not believe it is appropriate to codify the note to Special Provision 376 of the UNMR within the HMR currently, PHMSA acknowledges the value of the Special Provision 376 language in providing guidance on the shipment of damaged or defective batteries. Towards that end, PHMSA has issued a safety advisory notice on the shipment of damaged or defective batteries.[12] Within this safety advisory notice, PHMSA has paraphrased and cited the guidance presented in the note to Special Provision 376 of the UNMR for determining when a battery is damaged or defective. PHMSA encourages the shippers of damaged or defective batteries to review this notice for assistance in the shipment of damaged or defective lithium batteries.

D. Support for PHMSA's Decision Not To Propose Certain Amendments

DGAC provided comments on revisions in the 21st revised edition of the UNMR that contain packing instructions for several electric battery entries in the UNMR. The 21st revised edition of the UNMR contains amendments to Packing Instruction P801, applicable to used batteries assigned the following UN numbers: ''UN2794, Batteries, wet, filled with acid, electric storage;'' ''UN2795, Batteries, wet, filled with alkali, electric storage;'' and ''UN3028, Batteries, dry, containing potassium hydroxide solid, electric storage.'' These amendments were adopted to correct issues unique to the UNMR pertaining to the required use of stainless-steel boxes and plastic bins as packaging for these used batteries. DGAC provided comments in support of PHMSA's decision to not propose adopting these unique packaging requirements into the HMR and concurs with PHMSA's position that there is not a sufficient safety justification to limit the transport of used batteries. DGAC concludes the new provisions to P801 for these batteries would not substantially improve their safe transportation.

V. Section-by-Section Review of Amendments

The following is a section-by-section review of the amendments in this final rule.

A. Part 171

Section 171.7

Section 171.7 provides a listing of all voluntary consensus standards incorporated by reference into the HMR, as directed by the NTTAA. For this rulemaking, PHMSA evaluated updated international consensus standards pertaining to proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, air transport quantity limitations, and vessel stowage requirements. PHMSA contributed to the development of those updated standards—each of which build on the well-established and documented safety histories of earlier editions—as it participated in the discussions and working group activities associated with their proposal, revision, and approval. Those activities have, in turn, informed PHMSA's evaluation of the effect on safety those updated consensus standards would have when incorporated by reference and their provisions adopted into the HMR. Further, PHMSA notes that some of the consensus standards incorporated by reference within the HMR in this rulemaking have already been adopted into the regulatory schemes of other countries, noting again that PHMSA itself has issued an enforcement discretion authorizing their use as an interim strategy for complying with current HMR requirements. PHMSA is not aware of adverse safety impacts from that operational experience. For these reasons, PHMSA expects their adoption will maintain the high safety standard currently achieved under the HMR. PHMSA received a comment from DGAC in support of these incorporation by reference revisions. Therefore, PHMSA is adding or revising the following incorporation by reference materials:

- In paragraph (s)(1), incorporate by reference the 2018 edition of the IAEA Regulations for the Safe Transport of Radioactive Material, Safety Standards Series No. SSR–6 (Rev.1), to replace the 2012 edition, which is currently referenced in §§ 171.22; 171.23; 171.26; 173.415; 173.416; 173.417; 173.435; and 173.473. The IAEA regulations establish standards of safety for control of the radiation, criticality, and thermal hazards to people, property, and the environment that are associated with the transport of radioactive materials. Notable changes from the previous 2012 edition include clarification of certain marking requirements, a new group of surface contaminated objects SCO–III for ''UN2914,'' and amendments to basic radionuclide values (activity of the radionuclide as listed in § 173.435) for seven specific radionuclides (Ba-135m, Ge-69, Ir-193m, Ni-57, Sr-83, Tb-149 and Tb-161). The Regulations for the Safe Transport of Radioactive Material are available for download (free PDF) and purchase in hard copy on the IAEA website at: *https://www.iaea.org/publications/12288/regulations-for-the-safe-transport-of-radioactive-material.*
- In paragraph (t)(1), incorporate by reference the 2021–2022 edition of the ICAO Technical Instructions, to replace the 2019–2020 Edition, which is currently referenced in §§ 171.8; 171.22; 171.23; 171.24; 172.101; 172.202; 172.401; 172.407; 172.512; 172.519; 172.602; 173.56; 173.320; 175.10, 175.33; and 178.3. The ICAO Technical Instructions specify detailed instructions for the safe international transport of dangerous goods by air. The requirements in the 2021–2022 edition have been amended to better align with the 21st revised edition of the UNMR and the IAEA Regulations for the Safe Transport of Radioactive Material. Notable changes in the 2021–2022 edition of the ICAO Technical Instructions include new packing and stowage provisions, new and revised entries on the Dangerous Goods List, and editorial corrections. The 2021–2022 edition of the ICAO Technical Instructions are available for purchase on the ICAO website at *https://store.icao.int/en/shop-by-areas/safety/dangerous-goods.*
- In paragraph (v)(2), incorporate by reference the 2020 edition of the IMDG Code, Incorporating Amendment 40–20 (English Edition), to replace Incorporating Amendment 39–18, 2018 Edition, which is currently referenced in §§ 171.22; 171.23; 171.25; 172.101; 172.202; 172.203; 172.401; 172.407; 172.502; 172.519; 172.602; 173.21; 173.56; 176.2; 176.5; 176.11; 176.27; 176.30; 176.83; 176.84; 176.140; 176.720; 176.906; 178.3; and 178.274. The IMDG Code is a unified international code that outlines standards and requirements for the transport of dangerous goods by vessel. Notable changes in Amendment 40–20 include new packing and stowage provisions, new and revised entries on the Dangerous Goods List, and editorial corrections. Distributors of the IMDG Code can be found on the International

[12] See the ''Safety Advisory Notice for the Disposal and Recycling of Lithium Batteries in Commercial Transportation'' issued on May 17, 2022, at: *https://www.phmsa.dot.gov/news/phmsa-safety-advisory-notice-transportation-lithium-batteries-disposal-or-recycling.*

Maritime Organization (IMO) website at: *https://www.imo.org/en/publications/Pages/Distributors-default.aspx.*

• In paragraph (w), incorporate by reference or remove the following ISO documents to include new and updated standards for the specification, design, construction, testing, and use of gas cylinders:

—ISO 10156:2017, ''*Gas cylinders—Gases and gas mixtures—Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets*'' in paragraph (w)(38) and referenced in § 173.115. ISO 10156 specifies methods for determining whether a gas or gas mixture is flammable in air and whether a gas or gas mixture is more or less oxidizing than air under atmospheric conditions. It is intended to be used for the classification of gases and gas mixtures including the selection of gas cylinder valve outlets. This amendment removes ISO 10156:2010, third edition, and the associated corrigendum (ISO 10156:2010/Cor.1:2010(E)), from the HMR and adds the revised ISO 10156:2017(E), fourth edition, as the former documents have been withdrawn by ISO and replaced with the updated 2017 versions. As part of the five-year periodic review of all standards, ISO reviewed ISO 10156:2010 and published an updated version, ISO 10156:2017, which was published in September 2017 and adopted in the 21st revised edition of the UNMR. While many of the edits in this 2017 version were editorial changes made to suit the ISO publication rules, the standard has also been supplemented with a test method to determine the flammability limits of gases and gas mixtures in air and a calculation method to determine the lower flammability limit of a gas mixture. PHMSA expects that the latter change will enhance safety by providing improved instruction on the determination of flammability of gases and gas mixtures which aids in the proper selection of a valve. (*See* § 173.115 of the Section-by-Section Review of Amendments for additional discussion of this change).

—ISO 10297:2014/Amd 1:2017, ''*Gas cylinders—Cylinder valves—Specification and type testing*'' in paragraph (w)(42) and referenced in §§ 173.301b and 178.71. ISO published this supplemental amendment to the 2014 version of this document (*i.e.,* ISO 10297:2014) to clarify valve requirements for tubes and pressure drums and to correct errors found in the 2014 version. PHMSA references this amendment in §§ 173.301b and 178.71, where use of ISO 10297:2014 is required. PHMSA reviewed this document and determined that the amendments provide additional safety benefits for hazardous materials in transportation.

—ISO 10462:2013, ''*Gas cylinders—Transportable cylinders for dissolved acetylene—Periodic inspection and maintenance.*'' PHMSA is deleting the second edition of ISO 10462 currently in paragraph (w)(44) from the list of materials incorporated by reference. PHMSA requires the use of ISO 10462 for the requalification of a dissolved acetylene cylinder in § 180.207. In final rule HM–215N,[13] PHMSA incorporated by reference the updated third edition of ISO 10462; however, the rule included a sunset provision to allow continued used of this second edition until December 31, 2018. Because this date has since passed, and the second edition is no longer authorized for use under § 180.207, PHMSA is removing the reference to this edition in § 171.7, as well as making a conforming revision to remove the sunset provision in § 180.207.

—ISO 11114–1:2012/Amd 1:2017(E), ''*Gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 1: Metallic materials—Amendment 1.*'' In paragraph (w)(47), PHMSA is referencing—ISO 11114–1:2012/Amd 1:2017(E), in §§ 172.102, 173.301b, and 178.71. The 2017 ISO 11114–1:2012/Amd 1:2017(E) document supplements ISO 11114–1:2012(E), which provides requirements for the selection of safe combinations of metallic cylinder and valve materials, and cylinder gas contents. As part of ISO's regular five-year review of its standards, the 2012 version of this document was amended through the issuance of this supplemental document, ISO 11114–1:2012/Amd 1:2017(E). The ISO 11114–1:2012/Amd 1:2017(E) document amends the 2012 version by providing more explicit instructions on the permissible concentrations of gases containing halogens in aluminum cylinders. It also provides amended requirements for butylene, hydrogen cyanide, hydrogen sulfide and nitric oxide. Consequently, the 21st revised edition of the UNMR updated all references to the 2012 edition to include a reference to the supplemental amendment (ISO 11114–1:2012/Amd 1:2017(E)). PHMSA revises the HMR likewise, by amending Special Provision 379, §§ 173.301b and 178.71 where ISO 11114–1:2012(E) is permitted or required, to also require compatibility with ISO 11114–1:2012/Amd 1:2017(E).

—ISO 11119–1:2012(E), ''*Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 1: Hoop wrapped fibre reinforced composite gas cylinders and tubes up to 450 l,*'' found in paragraph (w)(55). This document specifies requirements for composite gas cylinders and tubes between 0.5 L and 450 L water capacity, for the storage and conveyance of compressed or liquefied gases. ISO 11119–1:2012(E) is currently incorporated by reference in § 178.71; however, PHMSA is further incorporating by reference in § 178.75 to allow for the use of this ISO standard for specification multi-element gas containers (MEGCs).

—ISO 11119–2:2012(E), ''*Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 2: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 l with load-sharing metal liners*'' found in paragraph (w)(57). ISO 11119–2:2012 specifies requirements for composite gas cylinders and tubes between 0.5 L and 450 L water capacity, for the storage and conveyance of compressed or liquefied gases. ISO 11119–2:2012(E) is currently incorporated by reference in § 178.71; however, PHMSA further incorporates by reference in § 178.75 use of this ISO standard for specification MEGCs.

—ISO 11119–2:2012/Amd.1:2014(E), ''Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 2: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 L with load-sharing metal liners, Amendment 1'' found in paragraph (w)(58). ISO 11119–2:2012/Amd. 1:2014(E) is currently incorporated by reference in § 178.71; however, PHMSA further incorporates by reference in § 178.75 the use of this ISO standard for specification MEGCs. This supplemental amendment was published to align the drop test originally provided in ISO 11119–2 with the drop test outlined in ISO 11119–3 ''*Gas cylinders of composite construction—Specification and test methods—Part 3: Fully wrapped fibre reinforced composite gas cylinders with non-load-sharing metallic or non-metallic liners*''.

[13] 82 FR 15796 (Mar. 30, 2017).

—ISO 11119–3:2013(E), ''*Gas cylinders of composite construction—Specification and test methods—Part 3: Fully wrapped fibre reinforced composite gas cylinders with non-load-sharing metallic or non-metallic liners*'' listed in paragraph (w)(60). This document is currently incorporated by reference in § 178.71; however, PHMSA is additionally incorporating by reference in § 178.75. ISO 11119–3:2013 specifies requirements for composite gas cylinders up to 150 L water capacity and composite tubes above 150 L water capacity and up to 450 L water capacity, for the storage and conveyance of compressed or liquefied gases.

—ISO 11119–4:2016, ''*Gas cylinders—Refillable composite gas cylinders—Design, construction and testing—Part 4: Fully wrapped fibre reinforced composite gas cylinders up to 150 l with load-sharing welded metallic liners,*'' in (w)(61), which PHMSA references in §§ 178.71 and 178.75. This standard provides requirements for composite gas cylinders with load-sharing welded liners between 0.5 L and 150 L water capacity and a maximum test pressure of 450 bar [14] for the storage and conveyance of compressed or liquefied gases. PHMSA is requiring UN composite cylinders and tubes to conform to this standard in § 178.71. *See* 178.71 of Section-by-Section Review of Amendments for additional discussion on this new incorporation by reference.

—ISO 14246:2014/Amd 1:2017, ''*Gas cylinders—Cylinder valves—Manufacturing tests and examinations—Amendment 1,*'' in paragraph (w)(71). PHMSA is adding a reference to this document in § 178.71. This one-page amendment, published in 2017, is intended for use in conjunction with ISO 14246:2014, which specifies the procedures and acceptance criteria for manufacturing testing and examination of cylinder valves that have been manufactured to achieve type approval. This 2017 document amends the 2014 version by updating the pressure test and leakproofness test specifically for acetylene valves. Consequently, the 21st revised edition of the UNMR updated all references to the 2014 edition to include a reference to the supplemental amendment (ISO 14246/Amd 1:2017). Therefore, PHMSA is likewise adding a reference to this supplement in § 178.71, which requires inspection and testing in accordance with ISO 14246:2014. *See* 178.71 of the Section-by-Section Review of Amendments for additional discussion.

—ISO 17879:2017, ''*Gas cylinders—Self-closing cylinder valves—Specification and type testing,*'' in paragraph (w)(75). PHMSA is adding a reference to this standard in §§ 173.301b and 178.71. This standard provides the design, type testing, marking, and manufacturing tests and examination requirements for self-closing cylinder valves intended to be fitted to refillable transportable gas cylinders used to transport compressed, liquefied, or dissolved gases.

—ISO 20475:2018, ''*Gas cylinders—Cylinder bundles—Periodic inspection and testing*'' in paragraph (w)(77). This standard provides the requirements for the periodic inspection and testing of cylinder bundles containing compressed, liquefied, and dissolved gas. PHMSA is adding a reference to this standard in § 180.207, which provides the requirements for requalification of UN pressure receptacles.

—All ISO standards are available for preview and purchase at: *https://www.iso.org/standards.html.*

• In paragraph (aa)(3), incorporate by reference the updated 2016 version of the OECD Guidelines for the Testing of Chemicals ''*Test No. 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method.*'' PHMSA is updating the version of OECD Guidelines for the Testing of Chemicals Test No. 431 referenced in § 173.137, to maintain alignment with the UNMR. This document is used for the identification of corrosive chemical substances and mixtures. This updated edition includes in vitro methods allowing for better differentiation between hazard categories, which had not been possible under earlier editions due to the limited set of well-known in vivo corrosive sub-category chemicals against which to validate in vitro testing results. Therefore, this updated test protocol may provide clearer distinctions between severe and less severe skin corrosives. OECD test methods can be found in the OECD iLibrary available at: *https://www.oecd-ilibrary.org/.*

• In paragraph (dd), incorporate by reference United Nations standards including:

—''*Recommendations on the Transport of Dangerous Goods—Model Regulations,*'' 21st revised edition (2019), Volumes I and II, in paragraph (dd)(1), which are referenced in §§ 171.8; 171.12; 172.202; 172.401; 172.407; 172.502; 172.519; 173.22; 173.24; 173.24b; 173.40; 173.56; 173.192; 173.302b; 173.304b; 178.75; and 178.274. The UNMR provide framework provisions promoting uniform development of national and international regulations governing the transportation of hazardous materials by various modes of transport. At its ninth session on December 7, 2018, the UNSCOE on the Transport of Dangerous Goods and on the GHS adopted amendments to the UNMR concerning, inter alia: electric storage systems (including lithium batteries installed in cargo transport units and defective batteries), explosives, infectious waste of Category A, waste gas cartridges, harmonization with the 2018 edition of IAEA's Regulations for the Safe Transport of Radioactive Material, listing of dangerous goods, update of LC50 values for some toxic gases, and use of in vitro skin corrosion methods for classification. Therefore, PHMSA is adopting this revised edition in order to reflect these important updates.

—The Manual of Tests and Criteria, 7th revised edition (2019), in paragraph (dd)(2), which is referenced in §§ 171.24, 172.102; 173.21; 173.56; 173.57; 173.58; 173.60; 173.115; 173.124; 173.125; 173.127; 173.128; 173.137; 173.185; 173.220; 173.221; 173.224; 173.225; 173.232; part 173, appendix H; 175.10; 176.905; and 178.274. The Manual of Tests and Criteria contains instruction for the classification of hazardous materials for purposes of transportation according to the UNMR. PHMSA replaces the sixth revised edition (2015) and the sixth revised edition, Amendment 1 (2017) with the 7th revised edition. The amendments adopted in 2018 for the 7th revised edition include: a full review of the text of the Manual to facilitate its use in the context of the GHS; a new test under test series 8 to determine the sensitiveness of a candidate ammonium nitrate, emulsion or suspension, or gel, intermediate for blasting explosive, to the effect of intense localized thermal ignition under high confinement; new provisions addressing classification of polymerizing substances for transport; stability tests for nitrocellulose mixtures (new Appendix 10); and a compilation of classification results on industrial nitrocellulose in accordance with Chapter 2.17 of the GHS, which can be used for the classification of industrial

[14] 1 Bar = 100 kPa = 14.504 psi.

nitrocellulose based products (new Appendix 11). Additionally, the Committee considered that the reference to the ''Recommendations on the Transport of Dangerous Goods'' in the title of the manual was no longer appropriate and decided that the manual should be entitled ''*Manual of Tests and Criteria.*'' Therefore, PHMSA amends the title of this document in the list of reference material in § 171.7 to reflect this change. Finally, PHMSA is adopting this revised edition in order to reflect these important updates.

—''*Globally Harmonized System of Classification and Labelling of Chemicals*'', eighth revised edition (2019) in paragraph (dd)(3), which is referenced in § 172.401. The GHS standard provides a basic scheme to identify the hazards of substances and mixtures and to communicate the hazards. At its ninth session on December 7, 2018, the Committee adopted a set of amendments to the 7th revised edition of the GHS which include, inter alia: new classification criteria, hazard communication elements, decision logics, and guidance for chemicals under pressure; new provisions for the use of in vitro/ex vivo data and non-test methods to assess skin corrosion and skin irritation; miscellaneous amendments to clarify the classification criteria for Specific Target Organ Toxicity; revised and further rationalized precautionary statements and an editorial revision of Sections 2 and 3 of Annex 3; new examples of precautionary pictograms to convey the precautionary statement ''Keep out of reach of children''; a new example in Annex 7 addressing labelling of sets or kits; and guidance on the identification of dust explosion hazards and the need for risk assessment, prevention, mitigation, and hazard communication. Therefore, PHMSA is adopting this revised edition in order to reflect these important updates.

—''*Agreement concerning the International Carriage of Dangerous Goods by Road,*'' in (dd)(4), which is referenced in § 171.23. The Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) outlines regulations concerning the international carriage of dangerous goods by road within the EU and other countries that are party to the agreement. PHMSA removes references to the 2019 edition of the ADR, ECE/TRANS/257, and adds references to volumes I and II and the corrigendum of the 2020 edition, ECE/TRANS/300. The ADR can be accessed at: *https://www.unece.org/trans/danger/publi/adr/adr_e.html*. The main changes to the 2020 edition include revisions to the P200 packaging section for cylinders and updates to reference various updated ISO publications. As such, PHMSA is adopting this revised edition in order to reflect these important updates.

The following standards are already incorporated by reference in the section(s) in which they appear in the regulatory text: ISO 10297:1999(E), ISO 10297:2006(E), ISO 10297:2014(E), ISO 10461:2005(E), ISO 10462:2013(E), ISO 10692–2:2001(E), ISO 10692–2:2001(E), ISO 11114–1:2012(E), ISO 11114–2:2013(E), ISO 11117:1998(E): ISO 11117:2008(E), ISO 11117:2008/Cor.1:2009(E): ISO 11118(E), ISO 11118:2015(E), ISO 11119–1(E), ISO 11119–2(E), ISO 11119–3(E), ISO 11120(E), ISO 11120:2015(E), ISO 11513:2011(E), ISO 11621(E), ISO 11623(E), ISO 11623:2015(E), ISO 13340:2001(E); ISO 13736:2008(E), ISO 14246:2014(E), ISO 16111:2008(E), ISO 16148:2016(E), ISO 17871:2015(E), ISO 18172–1:2007(E), ISO 20703:2006(E), ISO 21172–1:2015(E), ISO 22434:2006(E), and ISO/TR 11364:2012(E); European Directive 2010/35/EU; Transport Canada TDG Regulations; Test Nos. 404, 430, and 435.

Section 171.8

Section 171.8 defines terms used throughout the HMR that have broad or multi-modal applicability. Currently, the definitions provided in § 171.8 for SADT and SAPT—*i.e.,* ''self-accelerating decomposition temperature'' and ''self-accelerating polymerization temperature''—only spell out the abbreviations and direct users to § 173.21—Forbidden materials and packages—for the actual defining criteria. In the NPRM, we proposed to make editorial changes to improve the utility of the definitions of SADT and SAPT by providing a clear explanation of these terms in the context of packaging within the HMR. As such, DGAC provided comments in response to the NPRM in support of PHMSA's proposed revision of the definitions for SADT and SAPT; and confirmed that these changes will clarify understanding of these terms and assist selection of the proper packaging of these materials. Therefore, PHMSA is making editorial changes to improve the utility of the definitions of SADT and SAPT by providing a clear explanation of these terms in the context of packaging within the HMR.

Section 171.12

Paragraph (a) of § 171.12 prescribes requirements for the use of the TDG Regulations for hazardous materials transported from Canada to the United States, from the United States to Canada, or through the United States to Canada or a foreign destination. In this final rule, PHMSA amends § 171.12(a)(1) to authorize the use of a temporary certificate issued by Transport Canada for motor carrier or rail transportation of a hazardous material.

In a 2017 rulemaking—HM–215N [15]—PHMSA authorized hazardous materials to be offered for transportation or transported by motor carrier and rail in accordance with an equivalency certificate issued by Transport Canada, as an alternative to transportation of these items under the TDG Regulations as provided in § 171.22. The HMR amendment resulted from negotiations by the U.S.-Canada Regulatory Cooperation Council (RCC), a government-to-government forum established in 2011 by the President of the United States and the Canadian Prime Minister for PHMSA and Transport Canada, respectively, to identify and resolve—with input from stakeholders—impediments to cross-border transportation of hazardous materials. Among the initiatives agreed upon by PHMSA and Transport Canada within the RCC was modification of their respective regulations to ensure reciprocal recognition of special permits (PHMSA) and certificates (Transport Canada) specifying the terms and conditions authorizing deviations from their respective regulatory requirements governing transportation of hazardous materials.

Subsequently, Transport Canada recognized PHMSA's special permits, which are issued based on either being in the public interest or on the basis that the permit provides a demonstrable equivalent level of safety. *See* § 107.105(d). In HM–215N, PHMSA revised the HMR to recognize equivalency certificates by Transport Canada based on a finding of safety equivalence with the TDG Regulations. That rulemaking did not, however, reflect the fact that Transport Canada also issues temporary certificates authorizing deviation from the TDG Regulations on a finding that transportation of certain hazardous materials is in the public interest. Transport Canada issues temporary certificates after a technical review by its subject matter experts of an

[15] 82 FR 15796 (Mar. 30, 2017).

applicant's supporting documentation demonstrating shipment of the hazardous material is in the public interest. Temporary certificates are of limited duration and specify terms and conditions—often extensive—to mitigate risks to public safety and the environment. Transport Canada posts all temporary certificates to its publicly available website.[16]

PHMSA has evaluated Transport Canada's practices in reviewing and issuing temporary certificates and expects that PHMSA's recognition of those certificates for motor carrier or rail transportation of hazardous materials will not adversely affect safety. As noted above, Transport Canada issues those certificates only after a technical review is completed by its own subject matter experts to mitigate residual risks to public safety and the environment as outlined by the certificates' terms and conditions, including limiting duration of those temporary certificates. Additionally, other regulatory requirements (of Transport Canada or PHMSA) not excepted by a temporary certificate remain in effect. PHMSA further notes that, consistent with the HMR's existing authorization in § 171.12 for reliance on the TDG Regulations to authorize certain shipments in the United States, the new authorization to use a temporary certificate applies only for the duration of a shipment. In other words, once a shipment offered in accordance with a temporary certificate reaches its destination, any subsequent offering of packages imported under a Transport Canada temporary certificate must be completed in full compliance with the HMR. PHMSA's revisions to § 171.12 further mitigates risk to public safety and the environment by applying only to motor carrier and rail.

The recognition of Transport Canada-issued temporary certificates improves cross-border movement of hazardous materials responding to the COVID–19 public health emergency or other future emergencies. For example, among the temporary certificates recently issued by Transport Canada are several authorizing exceptions from TDG Regulations to enable movement of hand sanitizer chemicals and COVID–19 test samples.[17] These revisions to the HMR help to ensure that, should Transport Canada issue additional temporary certificates responding to the COVID–19 public health emergency or another cross-border threat to public safety or the environment, the HMR will not be an obstacle to those efforts. Dow, DGAC, and COSTHA all provided comments in support of the amendment to improve cross-border movement of hazardous materials. Commenters added that this revision will improve efforts in responding to the COVID–19 and other potential public health emergencies.

Section 171.23

Section 171.23 outlines the requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Transport Canada TDG Regulations, or the IAEA Regulations. It also includes provisions that authorize the use—under specific conditions—of pi-marked pressure vessels, which are pressure vessels and pressure receptacles that comply with ECE/TRANS/257, the ADR, and the EU Directive 2010/35/EU, and marked with a pi (π) symbol to denote such compliance. PHMSA is amending § 171.23(a) to update the reference to ECE/TRANS/257 to: (1) reference the 2020 edition of this document, ECE/TRANS/300; and (2) reference both volumes I and II of the ADR. Specifically, § 171.23(a) authorizes cylinders that comply with the requirements of Packing Instruction P200 (packing instruction for cylinders, tubes, pressure drums, and bundles of cylinders) or P208 (packing instruction for Class 2 adsorbed gases) and 6.2 (requirements for the construction and testing of pressure receptacles, aerosol dispensers, small receptacles containing gas (gas cartridges), and fuel cell cartridges containing liquefied flammable gas) of the ADR, published in 2019 as document ECE/TRANS/257. Upon review of the 2020 edition of this document, ECE/TRANS/300, PHMSA did not find any substantive changes to the provisions in 6.2, P200, or P208, and therefore, does not expect that incorporating by reference ECE/TRANS/300 will impose any safety risk or economic impact. However, updating the version incorporated by reference to reflect the edition that is currently in force facilitates access to foreign markets by U.S. manufacturers and businesses.

B. Part 172

Section 172.101 Hazardous Materials Table (HMT)

The HMT summarizes terms and conditions governing transportation of certain hazardous materials under the HMR. For each entry, the HMT identifies information such as the proper shipping name, UN identification number, and hazard class. The HMT specifies additional information or reference requirements in the HMR such as hazard communication, packaging, quantity limits aboard aircraft, and stowage of hazardous materials aboard vessels. In this final rule, PHMSA amends certain entries in the HMT to reflect the regulatory amendments discussed below in the Section-by-Section Review of Amendments. For purposes of the Government Publishing Office's typesetting procedures, changes to the HMT appear under three sections of the HMT: ''remove,'' ''add,'' and ''revise.'' Certain entries in the HMT, such as those with revisions to the proper shipping names, appear as a ''remove'' and ''add.'' Amendments to the HMT include the following:

New HMT Entries

- UN0511, Detonators, electronic programmable for blasting
- UN0512, Detonators, electronic programmable for blasting
- UN0513, Detonators, electronic programmable for blasting
- UN3549, Medical Waste, Category A, Affecting Humans, *solid or* Medical Waste, Category A, Affecting Animals *only, solid*

The UNMR contain a new entry to its Dangerous Goods List for regulated medical waste in Category A (*see* above list for UN3549). In the NPRM, PHMSA proposed to add this new entry for this proper shipping name and UN number and assigning Special Provision 131 to inform offerors that an approval is required when shipping this material.

DGAC and HWI provided comments supporting the inclusion of a new entry in the HMT for ''UN3549, Medical Waste, Category A, Affecting Humans, *solid or* Medical Waste, Category A, Affecting Animals *only, solid.*'' However, DGAC and HWI believe that PHMSA should include the corresponding packing provisions in the UNMR associated with ''UN3549, Medical Waste, Category A, Affecting Humans, *solid or* Medical Waste, Category A, Affecting Animals *only, solid.*'' DGAC asserts that PHMSA should accept the internationally recognized packaging for these materials as a part of the international harmonization process. Both DGAC and HWI believe that continuing to require special permits or approvals for the packaging of these materials does little to enhance transportation safety. HWI adds that the special permit process can take a significant amount of time and recommends that PHMSA provide

[16] See Transport Canada, ''Approvals—Search by Certificate Number,'' *https://wwwapps.tc.gc.ca/Saf-Sec-Sur/3/approvals-approbations/Search Certificates.aspx* (last visited Apr. 16, 2021).

[17] See Transport Canada, ''Temporary Certificates,'' *https://tc.canada.ca/en/dangerous-goods/temporary-certificates* (last visited Apr. 16, 2021).

initial packaging guidance for Category A medical wastes, so that generators have an immediate, safe, and compliant packaging solution.

PHMSA is adding ''UN3549, Medical Waste, Category A, Affecting Humans, *solid or* Medical Waste, Category A, Affecting Animals *only, solid*'' to the HMT in order to provide a more detailed proper shipping name for the shipment of biological waste. PHMSA acknowledges that in biological emergency response crises, such as the response to Ebola outbreaks, it is critical to have approved packagings for cleanup of biological waste. However, PHMSA asserts that due to the unknown nature of any infectious agent that may produce a category A biological waste, it is necessary to retain greater oversight of the safety and operational controls associated with approved packagings via the special permit process. PHMSA's special permit process can accommodate emergency processing of applications for instances associated with transportation of hazardous materials during a public health emergency or natural disaster. For these reasons PHMSA is not assigning baseline packaging provisions in the HMT for to the new proper shipping name ''UN3549, Medical Waste, Category A, Affecting Humans, *solid or* Medical Waste, Category A, Affecting Animals *only, solid.*'' However, PHMSA is assigning Special Provision 131 to state that approval from the Associate Administrator, through a special permit, is required when offering this material for transportation.

PHMSA assigns a new special provision, Special Provision 430, to specify the appropriate use of this proper shipping name. The addition of a proper shipping name that more specifically describes the material in transportation is expected to reduce regulatory burdens in shipping this material internationally and domestically. By limiting the scope of transport by way of special provision approval requirements for each shipment, PHMSA can exercise greater oversight of the transport of these materials to, from, or within the United States.

PHMSA is adding three new entries for the proper shipping name ''Detonators, electronic *programmable for blasting*'' with the following new UN numbers: UN0511, UN0512, and UN0513. These entries were added in the 21st revised edition of UNMR as result of a proposal from the Australian Explosives Industry and Safety Group (AEISG) and ensuing discussions held by the UN Working Group on Explosives (EWG) of the Sub-Committee of Experts on the Transport of Dangerous Goods in 2017 and 2018.[18] AEISG proposed adding new entries in the UNMR for electronic detonators to distinguish them from electric detonators, which have significantly different design characteristics.

The HMT has nine entries for detonators—not used for ammunition—which include: ''Detonators, non-electric for blasting,'' ''Detonators, electric for blasting,'' and ''Detonator assemblies, non-electric for blasting,'' which may fall in to one of three hazard classes (1.1B, 1.4B, or 1.4S). Under the hazardous materials classification scheme, based on the existing available entries, electronic detonators are required to be transported as ''Detonators, electric for blasting'' which is not the most accurate description. While using this name does not pose inherent risks during transportation, it creates potential for risks in down-stream storage, use, and handling operations. Because electronic detonators are significantly different from other electric and non-electric detonators, PHMSA is adding new entries for these devices rather than including them within the existing entries for electric detonator types. As with other explosives, the proper classification of these devices depends on packaging and testing, hence new entries must include all possible hazard classifications (1.1B, 1.4B, and 1.4S). For other newly added hazardous materials assigned a UN number on the Dangerous Goods List in the UNMR, PHMSA is adding: UN0511 (1.1B), UN0512 (1.4B), and UN0513 (1.4S) to the HMT to facilitate proper classification and handling across governmental and modal jurisdictions. PHMSA determined that this change provides clarity and enhanced safety by adding more specific proper shipping names to describe the difference between electronic detonators and electric detonators. PHMSA received a comment from IME in support of including these three new hazardous materials descriptions for electronic detonators in the HMT.

Column (1) Symbols

Section 172.101(b) describes column (1) of the HMT and symbols providing for additional requirements for transportation of listed hazardous materials that may be indicated in the column. As provided in § 172.101(b)(1): (1) the symbol ''A'' identifies a material that is subject to the requirements of the HMR only when offered or intended for transportation by aircraft; (2) the symbol ''W'' identifies a material that is subject to the requirements of the HMR only when offered or intended for transportation by vessel; and (3) the symbol ''I'' identifies proper shipping names which are appropriate for describing materials in international transportation. The UNMR were amended for consistency with the ICAO Technical Instructions to indicate that in addition to being regulated by vessel, the following entries are also regulated for air transport: ''UN1372, Fibers, animal *or* Fibers, vegetable *burnt, wet or damp,*'' ''UN1387, Wool waste, wet,'' ''UN1856, Rags, oily,'' ''UN1857, Textile waste, wet,'' and ''UN3360, Fibers, vegetable, dry.'' In the case of these particular entries, they are forbidden for air transport in the ICAO Technical Instructions. While reviewing this amendment, PHMSA found that all of these entries except for ''UN3360, Fibers, vegetable, dry,'' are also identified as only being regulated for air and vessel transportation as denoted by the symbols ''A'' and ''W'' in column (1). For UN3360, the symbols ''I'' and ''W'' are presently assigned in column (1) and the quantity limit in column (9) is ''No Limit'' for both passenger and cargo air. This is inconsistent with the ICAO Technical Instructions which forbid this material for transport by air. Therefore, consistent with the ICAO Technical Instructions for the UN3360 entry, PHMSA adds the symbol ''A'' to column (1) and amends column (9) to read ''Forbidden.'' This is further consistent with the entries for similar materials ''UN1372, Fibers, animal *or* Fibers, vegetable'' and ''UN1373, Fibers *or* Fabrics, animal *or* vegetable *or* Synthetic, n.o.s.'' that are also assigned the symbol ''A'' in column (1) and ''Forbidden'' in column (9). PHMSA determines that this change will facilitate international air transportation and save shippers time and costs by preventing delayed and rejected shipments.

Column (2) Hazardous Materials Descriptions and Proper Shipping Names

Section 172.101(c) describes column (2) of the HMT and the requirements for hazardous materials descriptions and proper shipping names. The UNMR contain the entry ''UN3363, Dangerous Goods in Articles *or* Dangerous Goods in Machinery *or* Dangerous Goods in Apparatus,'' in its Dangerous Goods List; however, the HMT entry UN3363 does not include ''Dangerous Goods in Articles or,'' in the proper shipping name. PHMSA is adding ''Dangerous Goods in Articles *or,*'' to the proper

[18] *https://unece.org/fileadmin/DAM/trans/doc/2018/dgac10c3/ST-SG-AC.10-C.3-2018-58e.pdf.*

shipping name. This change provides flexibility for shippers selecting the most appropriate proper shipping name by adding a third option in the proper shipping name associated with this UN Number. Additionally, for the proper shipping name ''Fuel system components (including fuel control units (FCU), carburetors, fuel lines, fuel pumps)'' which currently directs HMT users to ''see Dangerous Goods in Apparatus or Dangerous Goods in Machinery'', PHMSA is amending the directions to include a reference to ''Dangerous Goods in Articles.'' PHMSA expects that these changes will improve hazard communication by including a more specific description for articles containing hazardous materials.

Additionally, for the entry ''UN2522, 2-Dimethylaminoethyl methacrylate,'' PHMSA is adding the word ''stabilized'' to this proper shipping name to identify this material as a polymerizing substance. Discussions held by the UNSCOE identified ''UN2522, 2-Dimethylaminoethyl-methacrylate'' as having a similar molecular structure and polymerization behaviors to ''UN 3302, 2-Dimethylaminoethyl acrylate, stabilized.'' Under the HMR and international regulations, polymerizing substances require verification that a sufficient level of stabilization is provided prior to transportation. This requirement for stabilization is also indicated by assignment of Special Provision 387 in the HMT, which PHMSA adds for UN2522.

Finally, for the entry ''UN3171, Battery-powered vehicle or Battery-powered equipment,'' PHMSA is making an editorial change to italicize the ''or'' in the hazardous material description. Currently, the ''or'' is in roman type and not italicized. Section 172.101(c) introductory text instructs that proper shipping names are limited to those in roman type. Moreover, the current form of the entry is such that a person may confuse the proper shipping name with the whole description and not the option of ''Battery-powered vehicle'' or ''Battery-powered equipment.'' Therefore, PHMSA revises the entry to read ''Battery-powered vehicle *or* Battery-powered equipment.''

Column (5) Packing Group

Section 172.101(f) describes column (5) of the HMT, which specifies one or more packing groups—PG I, II, or III—assigned to certain materials. A PG designation indicates the required level of packaging according to the degree of danger presented by hazardous materials. PG I indicates the greatest level of danger, PG II corresponds to a medium level of danger, and PG III corresponds to a minor danger.

In the NPRM, PHMSA proposed to remove the assignment of PG II as indicated in column (5) for the entry ''UN3291, Regulated medical waste, n.o.s. *or* Clinical waste, unspecified, n.o.s. *or* (BIO) Medical waste, n.o.s. *or* Biomedical waste, n.o.s., *or* Medical Waste n.o.s.'' This entry is the only entry with a Division 6.2 classification that has PG II assigned in column (5).

HWI provided comments in support of harmonizing with international standards by removing the assignment of PG II from column (5) of the HMT for the ''UN 3291, Regulated medical waste, n.o.s.'' entry. However, HWI notes that ''PG II'' is currently widely utilized as part of the proper shipping description marking on regulated medical waste containers, of which many of their members have a significant inventory. HWI seeks confirmation that that packages with ''PG II'' printed on the package as part of the proper shipping description can still be used permissively.

PHMSA confirms that packages marked with ''PG II'' as part of the proper shipping name can permissively be used if the package otherwise complies with §§ 172.303 and 172.304 marking requirements. HWI further suggests PHMSA clarify that PG II containers are still required to meet the packaging requirements in § 173.197 and that the removal of the packing group from the HMT does not negate authorized packaging at the PG II performance level. PHMSA agrees that the PG II performance level requirements for packaging used for regulated medical waste in § 173.197 would still apply; however, we do not believe further clarification is necessary as we did not propose changes to the packaging provisions. It is clear that § 173.197 is assigned to ''UN3291'' material in the HMT for authorized non-bulk packagings, for example, and that the packaging requirements in paragraph (b) required UN standard packagings at the PG II performance level.

Therefore, PHMSA is amending this entry to not include PG II in column (5) of the HMT and to align with international regulations and § 172.101(f), which specifically states that Division 6.2 materials are not assigned packing groups in the HMR. For packaging purposes, any requirement for a specific packaging performance level is set out in the applicable packaging authorizations of part 173. Instead of having PG II indicated in Column (5), packaging provisions for these materials would continue to be outlined in § 173.197. PHMSA expects this editorial change will maintain the current level of safety as no packaging provisions are changing.

Column (6) Label Codes

Section 172.101(g) describes column (6) of the HMT, which contains label codes representing the hazard warning labels required for specific hazardous materials in the HMT. In the HM–215O final rule,[19] PHMSA added twelve HMT entries as part of a classification scheme for articles containing hazardous materials not otherwise specified by name (*i.e.,* n.o.s. entries) in the HMR. The entries were inadvertently added without label codes in column (6). PHMSA is correcting the entries here by adding the appropriate label codes to the following:

- UN3537, Articles containing flammable gas, n.o.s.
- UN3538, Articles containing non-flammable, non-toxic gas, n.o.s.
- UN3539, Articles containing toxic gas, n.o.s.
- UN3540, Articles containing flammable liquid, n.o.s.
- UN3541, Articles containing flammable solid, n.o.s.
- UN3542, Articles containing a substance liable to spontaneous combustion, n.o.s.
- UN3543, Articles containing a substance which in contact with water emits flammable gases, n.o.s.
- UN3544, Articles containing oxidizing substance, n.o.s.
- UN3545, Articles containing organic peroxide, n.o.s.
- UN3546, Articles containing toxic substance, n.o.s.
- UN3547, Articles containing corrosive substance, n.o.s.
- UN3548, Articles containing miscellaneous dangerous goods, n.o.s.

Column (7) Special Provisions

Section 172.101(h) describes column (7) of the HMT, which assigns special provisions for each HMT entry. Section 172.102 provides for the meaning and requirements of the special provisions assigned to entries in the HMT. The revisions to column (7) of certain entries in the HMT are discussed below. Also, *see* § 172.102 of the Section-by-Section Review of Amendments below for a detailed discussion of the special provision amendments addressed in this final rule.

Special Provisions 196 and 197

PHMSA is adding new Special Provision 196 to the following HMT

[19] 85 FR 27810 (May 11, 2020).

entries to outline thermal stability testing requirements for their transportation:

- UN0340, Nitrocellulose, *dry or wetted with less than 25 percent water (or alcohol), by mass*
- UN0341, Nitrocellulose, *unmodified or plasticized with less than 18 percent plasticizing substance, by mass*
- UN0342, Nitrocellulose, *wetted with not less than 25 percent alcohol, by mass*
- UN0343, Nitrocellulose, *plasticized with not less than 18 percent plasticizing substance, by mass.*

PHMSA is assigning new Special Provision 197 to the following entries in the HMT to outline thermal stability testing requirements for their transportation:

- UN2555, Nitrocellulose with water *with not less than 25 percent water, by mass*
- UN2556, Nitrocellulose with alcohol *with not less than 25 percent alcohol by mass, and with not more than 12.6 percent nitrogen, by dry mass*
- UN2557, Nitrocellulose, *with not more than 12.6 percent nitrogen, by dry mass* mixture with *or* without plasticizer, with *or* without pigment
- UN3380, Desensitized explosives, solid, n.o.s.

PHMSA received an anonymous comment on the proposal to add Special Provisions 196 and 197 for nitrocellulose products. These special provisions are intended to ensure nitrocellulose products are tested to verify they meet specific stability requirements to avoid the danger of self-ignition during transportation. The commenter notes that the special provisions state ''[t]he nitrocellulose must meet the criteria of the Bergmann-Junk test or methyl violet paper test in the UN Manual of Tests and Criteria, Appendix 10 (IBR, see § 171.7 of this subchapter).'' The commenter supports these revisions and believes they will ensure that Class 1 and Class 4 nitrocellulose products are tested to verify that the materials meet specific stability requirements to avoid the danger of self-ignition during transportation.

However, the anonymous commenter asserts that the stability of nitrocellulose is highly dependent upon storage conditions, and such testing at the time of manufacture does not necessarily guarantee stability during transportation (*i.e.,* transportation might happen a significant time after manufacturing and testing has occurred). Therefore, the commenter believes the text of Special Provisions 196 and 197 should additionally include a time criterion for testing nitrocellulose products to indicate how recently the testing for stability occurred. The commenter acknowledges that any time frame identified would require a discretionary evaluation of risks by PHMSA. However, even such discretionary decision-making would help ensure nitrocellulose products that may have decreased stability since testing are not put into transportation.

PHMSA notes that in discussions at UN subcommittee meetings, the Bergmann-Junk or methyl violet paper tests were compared to the normal thermal stability test. The overall conclusion was that the Bergmann-Junk or methyl violet paper tests did a better job in determining whether remaining nitric acids had been properly washed away during manufacture. If the acids are properly washed away during manufacture (as verified by the testing) the materials are unlikely to destabilize with time. PHMSA therefore understands that there should be low risk for future breakdown due to excess acids over time such as during storage. PHMSA further notes that the commenter's assumption that HMR requirements should address the low risk of these nitrocellulose products degrading over time is in tension with the HMR's approach regarding other hazardous materials of similar classification. For example, the current classification scheme in the HMR requires thermal stability testing before explosives are approved for transportation, but it does not explicitly require batch-specific testing every time a new shipment is made. The HMR places the responsibility on the manufacturer or offeror to ensure each batch is the same as the formulation that was approved. This means manufacturer or offeror often conducts a variety of tests on each batch for quality assurance purposes. Similarly, the classification scheme in the HMR makes no guarantees that materials approved for transportation can be stored for extended periods of time in any possible condition before subsequent transportation under their original approval. The HMR places responsibility on the offeror to ensure that their material has not decomposed or destabilized over time prior to transportation. Additionally, the burden lies with the offeror to ensure that the material does not need to be reclassified. Lastly, explosives that are known to be unstable or no longer meet the acceptance criteria would be considered forbidden explosives under § 173.54. Therefore, PHMSA does not agree with the commentor that a time frame is necessary for the stability testing required by Special Provisions 196 and 197.

Special Provision 360

PHMSA is assigning Special Provision 360 to the following HMT entries:

- UN3481, Lithium ion batteries, contained in equipment or packed with equipment *including lithium ion polymer batteries*
- UN3091, Lithium metal batteries, contained in equipment or packed with equipment *including lithium alloy batteries*

Special Provision 360 instructs that vehicles only powered by lithium batteries must be assigned the identification number UN3171. *See* SECTION 172.102 SPECIAL PROVISIONS for further discussion of Special Provision 360.

Special Provision 387

PHMSA is assigning Special Provision 387 to the HMT entry for ''UN2522, 2-Dimethylaminoethyl methacrylate.'' Special Provision 387 provides additional instructions for hazardous materials stabilized by chemical or temperature controls to ensure a level of stabilization prior to transportation sufficient to prevent the material from dangerous polymerization. The rationale for this change is discussed further below.

Portable Tank Special Provisions

PHMSA is removing and reserving Special Provisions TP39 and T41 for the PG II entry for ''UN2381, Dimethyl disulfide'' and the PG I entry for ''UN3148, Water-reactive liquid, n.o.s.'' respectively, as the transition period for continued use of certain portable tanks has expired. In the HM–215L final rule,[20] PHMSA added Special Provisions TP39 and TP41 to provide more time for portable tank transporters to transition their fleets in compliance with portable-tank specific requirements in Special Provisions T4 and T9. Special Provision TP39 authorized continued use of portable tank requirements in Special Provision T4 until December 31, 2018. Special Provision TP41 authorized the continued use of portable tank instruction T9 until December 31, 2018. Since that date has passed, TP39 and TP41 are no longer necessary.

Column (9) Quantity Limitations

Section 172.101(j) explains the purpose of column (9) in the HMT. Column (9) specifies quantity limitations for packages transported by

[20] 78 FR 987 (Jan. 1, 2013).

air and rail. Column (9) is divided into two columns: Column (9A) provides quantity limits for passenger aircraft/rail; and column (9B) provides quantity limits for cargo aircraft. The revisions only address transportation by aircraft, as the UNMR did not contemplate any changes to the limitations for transportation via rail.

The ICAO Technical Instructions have added provisions allowing ''UN2216, Fish meal, stabilized *or* Fish scrap, stabilized'' to be transported by aircraft when also meeting the provisions of ICAO Special Provision A219. Consistent with the ICAO Technical Instructions, PHMSA is amending Column 9 for this entry to indicate quantity limits for passenger and cargo aircraft of 100 kg and 200 kg, respectively.

As a conforming amendment, PHMSA also revises the § 173.218 packaging requirements for fish meal and fish scrap to reflect the authorization to transport this material by aircraft in addition to vessel. *See* SECTION 173.218 of the Section-by-Section Review of Amendments for further detail.

Column (10) Vessel Stowage

Section 172.101(k) explains the purpose of Column (10) of the HMT and prescribes the vessel stowage and segregation requirements for specific entries. Column (10) is divided into two columns: Column (10A) [Vessel stowage] specifies the authorized stowage locations on board cargo and passenger vessels; and Column (10B) [Other provisions] specifies special stowage and segregation provisions.

In Column (10A) for the entry for ''UN3135, Water-reactive solid, self-heating, n.o.s., PG I,'' consistent with the IMDG Code, PHMSA is amending the assigned stowage category from ''E'' to ''D.'' This revision means the material must be stowed ''on deck only'' on a cargo vessel or on a passenger vessel carrying a number of passengers limited to the greater of 25 passengers total or one passenger for each 3 meters of overall vessel length; transport is prohibited on a passenger vessel in which those passenger limits have been exceeded. Stowage category ''E'' is currently assigned to this material which allows ''under deck'' storage. The IMDG Code previously only authorized this material for transportation with the approval of the competent authority through the application of Special Provision 76. The IMDG Code has removed this special provision and the associated approval requirement and provided all necessary transport provisions for this commodity. This revision is consistent with the stowage category for other Division 4.3, PG I, materials with subsidiary hazards that are also assigned stowage category ''D'' for ''on deck only'' stowage and the IMDG Code assigned stowage category. For the ''UN2900, Infectious substances, affecting animals *only*'' and ''UN2814, Infectious substances, affecting humans,'' PHMSA is amending the assigned stowage category from ''B'' to ''E.'' This revision allows ''on deck'' or ''under deck'' stowage but does not allow stowage onboard when the number of passengers exceeds 25. This revision aligns with the IMDG Code assignment of this stowage category to these materials and is not expected to materially change the nature of authorized transport options for these materials.

Additionally, consistent with revisions to the IMDG Code, PHMSA makes numerous revisions to the special stowage and segregation provisions indicated in column (10B) of the HMT, labeled ''other provisions.'' PHMSA is assigning stowage code 52, which requires stowage ''separated from'' acids, to several entries in the HMT that are in a group of chemicals called alcoholates. Segregation from acids is currently not required by the HMR for these materials. However, alcoholates are strong alkaline substances that react vigorously with acids. Stowage code 52 is assigned to the following HMT entries:

- UN1289, Sodium methylate solutions *in alcohol*
- UN1431, Sodium methylate
- UN3206, Alkali metal alcoholates, self-heating, corrosive, n.o.s.
- UN3274, Alcoholates solution, n.o.s., *in alcohol*

For the entries ''UN2900, Infectious substances, affecting animals *only*'' and ''UN2814, Infectious substances, affecting humans,'' PHMSA is adding stowage codes 13 and 95 and new stowage code 155. Stowage codes 13 and 95 require keeping material as dry as reasonably practicable and stowage ''separated from'' foodstuffs. The IMDG Code has varying levels of stowage either ''away from'' or ''separated from'' foodstuffs depending on the type of shipment (*e.g.,* containerized or break-bulk). PHMSA is adding the more restrictive ''separated from,'' regardless of the type of shipment. The stowage of these materials separated from foodstuffs is expected to prevent inadvertent cross contamination of foodstuffs. New stowage code 155 requires vessel carriers to keep handling of the packages to a minimum and to inform the appropriate public health authority or veterinary authority where persons or animals may have been exposed to the package contents. Additionally, this handling restriction and communication requirement may facilitate reducing exposure and contract tracing surrounding UN2814 packages that contain COVID–19 materials. Except for the general ''separated from'' language, these revisions are consistent with IMDG Code requirements.

Additionally, for the PG III entry of ''UN3129, Water-reactive liquid, corrosive, n.o.s.,'' and for the PG II and III entries for ''UN3132, Water-reactive solid, flammable, n.o.s.,'' and ''UN3135, Water-reactive solid, self-heating, n.o.s.,'' which are all water reactive Division 4.3 materials, PHMSA is adding stowage code 85 to column (10B). Stowage code 85 requires ''under deck'' stowage in mechanically ventilated spaces. This revision is intended to ensure that if the cargo is stowed under deck, adequate mechanical ventilation is provided. Mechanical ventilation is important to ensure any potentially dangerous gases or vapors released are expelled from the cargo hold and not allowed to build up below deck.

PHMSA adds stowage code 156 to the lithium battery entries ''UN3090, Lithium metal batteries,'' ''UN3091, Lithium metal batteries contained in equipment, or Lithium metal batteries packed with equipment,'' ''UN3480, Lithium ion batteries,'' and ''UN3481, Lithium ion batteries contained in equipment or Lithium ion batteries packed with equipment'' in the HMT in column (10B). This new stowage code assignment requires that, in lieu of the stowage category A assigned in column (10A) in the current HMR which allows stowage ''on deck'' or ''under deck,'' lithium batteries that are offered in transportation for purposes of disposal or recycling, or that are offered under damaged, defective, or recalled provisions (*see* § 173.185(f) of the HMR), are required to be stowed in accordance with stowage category C which requires ''on deck only'' stowage on cargo and passenger vessels. PHMSA expects that this new stowage code will enhance the safety of shipment of lithium batteries expected from anticipated increases in use of lithium batteries in the transportation and other economic sectors in the years ahead. PHMSA received a comment from MDTC in support of this proposal.

PHMSA adds stowage code 157 to column (10B) for numerous entries in the HMT. Stowage code 157 requires aerosols, small receptacles containing gas, or gas cartridges transported for

purposes of recycling or disposal, to be stowed in accordance with stowage category C, which requires ''on deck only'' stowage, and be clear of living quarters. This stowage code requirement is in lieu of the stowage category A assigned in column (10A) in the current HMR allowing ''on deck'' or ''under deck'' stowage. PHMSA adds new stowage code 157 to the following entries in the HMT:

- UN1950, Aerosols, *corrosive, Packing Group II or III, (each not exceeding 1 L capacity)*
- UN1950, Aerosols, *flammable, (each not exceeding 1 L capacity)*
- UN1950, Aerosols, flammable, n.o.s. *(engine starting fluid) (each not exceeding 1 L capacity)*
- UN1950, Aerosols, *non-flammable, (each not exceeding 1 L capacity)*
- UN1950, Aerosols, *poison, Packing Group III (each not exceeding 1 L capacity)*
- UN2037, Gas cartridges, *(flammable) without a release device, non-refillable*
- UN2037, Receptacles, small, containing gas *or* gas cartridges *(flammable) without release device, not refillable and not exceeding 1 L capacity*
- UN2037, Receptacles, small, containing gas *or* gas cartridges *(non-flammable) without release device, not refillable and not exceeding 1 L capacity*
- UN2037, Receptacles, small, containing gas *or* gas cartridges *(oxidizing), without release device, not refillable and not exceeding 1 L capacity*

Section 172.102 Special Provisions

Section 172.102 lists special provisions applicable to the transportation of specific hazardous materials. Special provisions contain various provisions including packaging requirements, prohibitions, and exceptions applicable to particular quantities or forms of hazardous materials. PHMSA is making the following revisions to the special provisions in this section:

Special Provision 47

Special Provision 47 allows mixtures of solids that are not subject to the HMR and Class 3 flammable liquids to be transported as flammable solid material described as ''UN3175, Solids containing flammable liquid, n.o.s., 4.1,'' without applying the Division 4.1 classification criteria. This classification is permitted provided that there is no free liquid visible at the time the material is loaded or at the time the packaging is closed. In addition to providing classification testing relief for these items, this special provision provides further relief from the HMR for packets and articles, generally referred to as small inner packagings, if they contain less than 10 mL of a Class 3 liquid (in Packing Group II or III) and if the liquid is absorbed (*i.e.,* no free liquid in the packet or article) onto a solid material. This special provision is widely used for articles such as alcohol wipes, and due to the ongoing COVID–19 public health emergency, these items are being transported in increasing numbers to meet demand. While many of these wipes, depending on how they are packed, meet the conditions of this special provision and qualify for exception from regulation, confusion around the wording of the packaging conditions to qualify for the exception has led to an editorial amendment in the ICAO Technical Instructions.

On December 31, 2020, in an addendum to the 2021–2022 edition of the ICAO Technical Instructions, Special Provision A46 was amended to remove a reference to ''small inner packaging'' related to the sealed packets and articles. Prior to this amendment—and as currently provided in the HMR in Special Provision 47—it reads that to be excepted from the HMR, ''small inner packagings consisting of sealed packets and articles containing less than 10 mL of a Class 3 liquid in Packing Group II or III absorbed onto a solid material are not subject to this subchapter provided there is no free liquid in the packet or article.'' The phrasing is ambiguous enough that shippers may misinterpret the language as instructing them to pack small inner packagings with the sealed packets or articles. Instead, the intent of ''small inner packagings'' was to describe sealed packets and articles. The amendment to Special Provision A46 in the ICAO Technical Instructions is consistent with other provisions in the ICAO Technical Instructions; for example, Special Provision A158 clearly states that sealed packets and articles containing less than 10 mL of an environmentally hazardous liquid are not subject to the requirements when certain conditions are met. PHMSA agrees with the amendment made in the ICAO Technical Instructions removing the reference to ''small inner packagings'' to avoid confusion and makes the same revision in Special Provision 47 to clarify the exception within the HMR. PHMSA expects this clarification will facilitate the transport of hygienic products intended to prevent the spread of COVID–19.

Special Provision 134

Special Provision 134 provides instruction on the use of the HMT entry ''UN3171, Battery-powered vehicle *or* Battery-powered equipment,'' stipulating that it applies only to vehicles or equipment powered by wet batteries, sodium batteries, lithium metal batteries, or lithium ion batteries that are transported with these batteries installed. PHMSA amends language in Special Provision 134 to clarify its use in connection with lithium batteries installed in cargo transport units. Under this amendment, these items are described by a separate entry in the HMT, specifically, ''UN3536, Lithium batteries installed in cargo transport unit'' for which there are unique transportation requirements that do not apply to transport of battery-powered vehicles or equipment. PHMSA also amends the language in this special provision to replace the phrase ''consigned under'' with the phrase ''described using'' to provide a more easily-accessible, plain language understanding of the requirement. These amendments will clarify the requirements for packaging, marking, and transport of lithium batteries and ensure safe transport.

Special Provision 135

Special Provision 135 provides instruction for selecting the appropriate proper shipping name for vehicles with internal combustion engines powered by various fuel sources, such as a flammable gas, flammable liquid, or fuel cell. PHMSA amends Special Provision 135 to specify that lithium batteries installed in cargo transport units (UN3536), which are designed only to provide power external to the transport unit, may not be classified as an internal combustion engine installed in a vehicle. PHMSA expects that adding this clarifying language will avoid misclassifying lithium batteries in cargo transport units. Additionally, consistent with revisions to Special Provision 134, PHMSA amends the language in this special provision to replace the phrase ''consigned under'' with the phrase ''described using'' to the entries to provide consistency across similar provisions and improve understanding of the requirement.

Special Provision 136

Special Provision 136 provides instructions regarding the use of the HMT entry ''UN3363, Dangerous Goods in Apparatus *or* Dangerous Goods in Machinery'' and indicates that this UN number and the associated proper shipping names are only applicable to

machinery and apparatus containing hazardous materials as an integral element of the machinery or apparatus. In light of the addition of ''Dangerous Goods in Articles'' to the list of acceptable proper shipping names for UN3363 (*see* § 172.101 of the Section-by-Section Review of Amendments), PHMSA revises this special provision to add the words ''articles'' where machinery and apparatus are mentioned. PHMSA expects this revision to improve consistency across HMR provisions where UN3363 is discussed, thus enhancing safety.

Special Provision 147

Special Provision 147, assigned to UN3375, provides instruction on the description and classification criteria for non-sensitized emulsions, suspensions, and gels consisting mostly of ammonium nitrate and fuel, intended to produce a Type E blasting explosive only after further processing prior to use, which are transported as ''UN3375, Ammonium nitrate emulsion *or* Ammonium nitrate suspension *or* Ammonium nitrate gel, intermediate for blasting explosives.'' Currently, the HMR requires applicants to pass Test Series 8(a), (b), and (c) of the UN Manual of Tests and Criteria, when requesting an approval for transportation under UN3375. However, PHMSA is revising the last sentence of Special Provision 147 by removing the specific requirement to pass Tests 8(a), (b), and (c), so that eligible materials can pass Test Series 8(e) in lieu of 8(c) of the UN Manual of Tests and Criteria. Modifying Special Provision 147 will align with the equivalent special provision in the UNMR (SP 309) which was amended similarly. PHMSA makes this revision to reflect and allow for the inclusion of an additional test in the Test Series 8 provided in the UN Manual of Tests and Criteria. In the 7th revised edition UN Manual of Tests and Criteria Test Series 8 was expanded to include Test 8(e) as an alternative to 8(c). This change in testing was the result of technical discussions and amendment proposals held during UNSCOE meetings. At the 47th session of the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods, the EWG concluded that the UN Test 8(c) may be unsuitable for some ammonium nitrate emulsions which could lead to a false positive under certain conditions.[21]

PHMSA expects that removing this requirement to specifically pass the 8(c) test and alternatively pass the 8(e) test will reduce the risk of receiving a false positive result and consequently inaccurate classification. It also allows shippers the ability to perform additional classification testing as provided in the 7th revised edition of the UN Manual of Tests and Criteria.

Special Provisions 196 and 197

PHMSA is adding Special Provisions 196 and 197 pertaining to transportation of nitrocellulose. These new special provisions require that manufacturers of nitrocellulose products ensure that these Class 1 and Class 4 materials employ certain tests verifying that the materials meet specific stability requirements to avoid the danger of self-ignition. Those test methods determine whether a material is stable when subjected to elevated temperatures in transportation, which is critical to the safe transportation of materials such a nitrocellulose. Special Provision 196 applies to nitrocellulose materials in Class 1 (UN0340, UN0341, UN0342, and UN0343), and specifically excepts those materials from Type 3(c) thermal stability testing. Special Provision 197 is assigned to nitrocellulose materials in Class 4 (UN2555, UN2556, UN2557, and UN3380).

Special Provision 360

Special Provision 360 provides instruction to aid in proper identification of a battery-powered vehicle that contains lithium batteries. Currently, Special Provision 360 states that vehicles powered solely by lithium batteries must be identified as ''UN3171, Battery-powered vehicle *or* Battery-powered equipment.'' In the HM–215O final rule, PHMSA added a new UN entry, ''UN3536, Lithium batteries installed in cargo transport unit *lithium ion batteries or lithium metal batteries.*'' PHMSA is revising Special Provision 360 to better distinguish between the various types of equipment with lithium batteries. The revised language specifies that lithium batteries that are installed in cargo transport units which are designed only to provide power external to the transport unit must be transported as ''UN3536, Lithium batteries installed in a cargo transport unit *lithium ion batteries or lithium metal batteries,*'' making them subject to packaging provisions and exceptions outlined in Special Provision 389. The intent of this language is to clarify further that these batteries should not be described and transported as ''UN3091, Lithium metal batteries, contained in equipment *including lithium alloy batteries*'' or ''UN3481, Lithium ion batteries, contained in equipment *including lithium ion polymer batteries.*''

Furthermore, Special Provision 360 was originally assigned to the HMT entry ''UN3091, Lithium batteries, contained in equipment,'' however, in final rule HM–224F,[22] PHMSA adopted separate entries based on the lithium battery chemistry, *i.e.,* ''UN3091, Lithium metal batteries, contained in equipment *including lithium alloy batteries*'' or ''UN3481, Lithium ion batteries, contained in equipment *including lithium ion polymer batteries.*'' In doing so, PHMSA inadvertently did not make a conforming revision to assign Special Provision 360 to these separate descriptions in the HMT. Consistent with the revisions to Special Provision 360 to clarify appropriate use of descriptions for lithium battery equipment, PHMSA is assigning this special provision to the two lithium battery descriptions for contained in equipment and packed with equipment. Finally, PHMSA is also revising the text ''assigned to'' to read ''described using'' to improve understanding of the special provision instruction. In response to this proposal in the NPRM, COSTHA provided a comment in support of this revision.

Special Provision 370

Special Provision 370 is currently assigned to ''UN0222, Ammonium nitrate, *with more than 0.2 percent combustible substances, including any organic substance calculated as carbon, to the exclusion of any other added substance.*'' The entry UN0222 (1.1D) is intended for certain ammonium nitrates that are not a commercially manufactured product and this entry is typically used to identify contaminated ammonium nitrate or ammonium nitrate fertilizers that give a positive result when tested in accordance with Test Series 2 of the UN Manual of Tests and Criteria. However, Special Provision 370 currently states that a hazardous material may also be classified as UN0222 even if it has more that 0.2 percent combustible substances. PHMSA amends special provision 370 to better clarify when the entry for UN0222 may be applied. Clarifying this classification instruction is necessary to ensure that more readily transported materials—such as ammonium nitrate mixed with fuel oil (ANFO)—are not improperly transported as UN0222, which should be reserved for special non-commercial purposes. Given that inappropriately classified items pose an inherent safety risk to emergency responders, PHMSA revises Special Provision 370 to provide clarifying

[21] *https://unece.org/fileadmin/DAM/trans/doc/2018/dgac10c3/UN-SCETDG-53-INF22e.pdf.*

[22] 79 FR 46012 (Aug. 16, 2014).

language to ensure that certain ammonium nitrate materials (such as ANFO) are not described and classified as ''UN0222, Ammonium nitrate.'' Specifically, the amendment to this special provision stipulates that this UN entry should not be used when other applicable proper shipping names exist.

Special Provision 379

Special Provision 379 provides conditions for exception from full regulation under the HMR for anhydrous ammonia adsorbed or absorbed on a solid contained in ammonia dispensing systems or receptacles intended to form part of such systems. Among these conditions, Special Provision 379 requires that receptacles containing adsorbed or absorbed ammonia must be made of a material compatible with ammonia as specified in ISO 11114–1:2012(E), ''Gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 1: Metallic materials.'' PHMSA revises language in Special Provision 379 to add a reference to an amendment to ISO standard 11114–1:2012(E), specifically, ISO 11114–1:2012/Amd 1:2017(E) and correct the unintentional omission of the (E) to indicate the English language edition. As part of ISO's regular five-year review of its standards, the 2012 version of this document was amended through the issuance of document ISO 11114–1:2012/Amd 1:2017(E). The amended ISO standard provides more explicit instructions on the permissible concentrations of gases containing halogens in aluminum cylinders. It also provides amended requirements for butylene, hydrogen cyanide, hydrogen sulfide, and nitric oxide. Consequently, the 21st revised edition of the UNMR updated all references to the 2012 edition to include a reference to the amendment (ISO 11114–1:2012/Amd 1:2017(E)). PHMSA makes similar conforming revisions. *See* SECTION 171.7 Section-by-Section Review of Amendments discussion. In the course of its review of the 2017 amendment for ISO standard 11114, PHMSA determined that it enhances safety of transport and therefore, is appropriate for inclusion as an updated condition for transport of ammonia dispensing systems or receptacles intended to form part of such systems.

Special Provision 430

PHMSA adds Special Provision 430 and assigns it to the new HMT entry ''UN3549, Medical Waste, Category A, Affecting Humans, *solid or* Medical Waste, Category A, Affecting Animals *only, solid*'' discussed above. As with other special provisions that provide instruction pertaining to appropriate use of proper shipping names, PHMSA is adding Special Provision 430 to stipulate that only solid medical waste of Category A, which is being transported for disposal, may be described using this entry. The intent of this added language is to simplify the regulations and ensure proper classification of medical wastes to ensure safe transportation.

Special Provision 441

The UNMR and the IMDG Code contain an exception in their Special Provision 274 pertaining to ''UN3077, Environmentally hazardous substance, solid, n.o.s.'' and ''UN3082, Environmentally hazardous substance, liquid, n.o.s.'' Special Provision 274 requires a proper shipping name to be supplemented with a technical name, in the same manner as the letter ''G'' is assigned in the HMT. When a ''G'' is listed in Column (1) of the HMT in association with a particular entry, the proper shipping name must be supplemented with a technical name. For context, in both the UNMR and the HMT, when generic proper shipping names are used—*e.g.,* n.o.s. proper shipping names—a technical name must be provided as part of the basic description to provide additional information for hazard communication related to the material being shipped. For example, the HMT entry ''UN1760, Corrosive liquid, n.o.s.,'' provides a generic description of a corrosive liquid and, therefore, marking and shipping papers requirements necessitate a technical name pertaining to the corrosive liquid (*e.g.,* octanoyl chloride).

The new exception in Special Provision 274 modifies the requirement to supplement the proper shipping name with a technical name. The revision, which is specifically for materials shipping under UN3077 or UN3082, allows the use of a proper shipping name found on the Dangerous Goods List (the IMDG Code and UNMR' equivalent of the HMT) to be used in place of a technical name, provided that it does not: (1) include ''n.o.s.'' as part of the proper shipping name and; (2) is not an entry assigned Special Provision 274. In practice, this means that items, such as paint, that might be shipped as ''UN3082, Environmentally hazardous substance n.o.s.,'' are no longer required to include a supplemental technical name, and instead are permitted to include the more readily-recognizable name of the commodity (paint) on markings and shipping papers. For common commodities such as paint with various chemical components, emergency responders rely less on determining the specific chemical for performance of emergency response and respond to the known hazards of the commodity. PHMSA expects streamlining the hazardous material description requirements in this manner will help facilitate appropriate emergency response without a reduction in safety.

While the UNMR broadly provided this relief for UN3077 and UN3082, environmentally hazardous materials classified under these UN numbers are applicable to a narrower scope of materials under the IMDG Code. Under the IMDG Code, ''environmentally hazardous substances'' are those that are pollutants specifically for aquatic environments (which is equivalent to marine pollutants under the HMR) whereas the UNMR are broadly applicable to aquatic and other environments.

PHMSA is mirroring the expansion by the UNMR and IMDG Code's Special Provision 274 of acceptable technical names for marine pollutants transported under UN3077 and UN3082 by adding a new Special Provision 441 to the HMR. This special provision provides the same shipping description flexibility specifically for marine pollutants by removing the requirement to supplement the proper shipping name associated with UN3077 and UN3082 with a technical name. PHMSA is also modifying §§ 172.203(l) and 172.322 to maintain alignment with the IMDG Code with regard to the documentation and marking requirements when marine pollutant components are present in hazardous materials. In addition to providing logistical benefits for shippers, PHMSA expects that the use of readily recognizable common commodity names instead of technical names will facilitate emergency response by making the hazardous material more quickly and easily identifiable. *See* §§ 172.203(l) and 172.322 of the Section-by-Section Review of Amendments for additional discussions on revisions related to this amendment.

Special Provisions TP39 and TP41

PHMSA is removing and reserving portable tank special provisions TP39 and TP41. The sunset provisions in special provisions TP39 and TP41 allowing use of other portable tank special provisions expired on December 31, 2018, and thus, PHMSA removes them from the HMR to prevent the use of these expired provisions. *See* § 172.101 of the Section-by-Section Review of Amendments for further

detail of the deletion of these portable tank special provisions from the HMR.

Section 172.203

Section 172.203 prescribes additional description requirements for shipping papers. PHMSA is revising paragraphs (i)(2) and (l)(1) and adding new paragraphs (i)(4) and (q). Each revision is further described below, along with PHMSA's rationale for the revisions.

In paragraph (i), which provides requirements specific to vessel transportation, PHMSA is clarifying that the documentation of the flashpoint on shipping papers, as required in paragraph (i)(2), is only required for liquid hazardous materials that have a primary or subsidiary hazard of Class 3 and a flashpoint of 60 °C or below (in °C closed-cup (c.c.)). This revision aims to prevent the shipping delays resulting from confusion on how this documentation requirement applies to items for which flashpoint is not an appropriate classification criterion (*e.g.,* aerosols and flammable solids). Furthermore, limiting the flashpoint information to a narrower subset of hazardous materials ensures identifying information of the materials in transport better aligns with the material properties of those materials because flashpoint is a safety-relevant criterion only for hazardous materials that are liquids with a main or subsidiary hazard of Class 3. PHMSA does not expect any reduction in safety as a result of this editorial revision given that this revision ensures that information regarding the flashpoint is only provided for items in which flashpoint is a safety-relevant criterion; avoidance of the delays in transportation experienced in the past also reduces the risks associated with that transportation. PHMSA received comments in response to the NPRM from DGAC and Dow in support of this revision.

PHMSA is also adding a new paragraph (i)(4), that requires shipments of lithium batteries that are offered into transportation for purposes of disposal or recycling or offered under the damaged or defective provisions in § 173.185(f), to indicate on shipping papers one of the following disclaimers, as appropriate: ''DAMAGED/DEFECTIVE,'' ''LITHIUM BATTERIES FOR DISPOSAL,'' or ''LITHIUM BATTERIES FOR RECYCLING.'' This revision is consistent with revisions adopted in the IMDG Code and associated with an additional revision to § 176.84 of the HMR to require lithium batteries that are damaged or defective—or those that are being transported for disposal or recycling—to be stowed in accordance with stowage category C requirements authorizing ''on deck only'' stowage instead of the currently-authorized ''on deck'' or ''under deck'' options. This additional shipping paper requirement helps communicate information about the batteries to individuals making stowage plans for the vessel, provide a mechanism for ensuring the ''on deck'' stowage of these materials, and allow for more easily identifiable and effective response actions in the event of a fire involving lithium batteries onboard a vessel. PHMSA expects that these revised shipping requirements will contribute to the safe transportation of increased volumes of damaged/defective/recycled lithium batteries anticipated as a result of the increased use of lithium batteries in the transportation and other economic sectors. PHMSA received comments from DGAC, Dow, and MDTC in support of this revision. For additional information on this stowage requirement, *see* SECTION 176.84 of the Section-by-Section Review of Amendments.

In paragraph (l)(1), PHMSA is revising the scope of hazardous materials for which a specific marine polluting component must be identified in association with the basic description—*i.e.,* the combination of the UN number, proper shipping name, hazard class, and packing group—on a shipping paper. Currently, § 172.203(l) specifies that, when the proper shipping name for a hazardous material which is a marine pollutant does not identify the component that makes the hazardous material a marine pollutant, the name of the marine pollutant constituent must appear in parentheses within the basic description. PHMSA revises paragraph (l)(1) to limit the scope of this requirement to make it applicable only to generic HMT entries (as indicated by the G in Column 1 on the HMT) as well as those that have ''n.o.s.'' as part of the proper shipping name. The intent of this amendment is to extend the documentation and marking flexibility provided by Special Provision 441 (which currently applies only to environmentally hazardous substances (UN3077 and UN 3082)) and to other hazardous materials that may contain components(s) that are marine pollutants. For example, under the current HMR, if ''UN1263, Paint'' contains marine pollutants, the basic description required on shipping papers and markings have to include the specific marine polluting component(s) that are present in the paint, in addition to the words ''marine pollutant'' (*e.g.,* ''UN1263, Paint, 3 (propyl acetate, di-n-butyltin di-2-ethylhexanoate) MARINE POLLUTANT''). But under this amendment, the basic description for ''UN1263, Paint'' no longer require the addition of the ''marine pollutant'' language. Given that emergency responders do not depend on the specific technical name provided in association with the shipping description to effectively respond to emergencies, PHMSA expects streamlining the description to provide more readily recognizable and usable information that reflects the hazardous materials involved may facilitate emergency response. PHMSA received a comment from DGAC in support of this revision.

Finally, PHMSA is adding a new paragraph (q) to this section to require documentation of the holding time for refrigerated liquefied gases transported in portable tanks. Holding time is the span of time, as determined by testing, that elapses from the time of loading until the pressure of the contents, under equilibrium conditions, reaches the set point for the lowest pressure control valve or pressure relief valve setting. PHMSA will require including the specific date when the holding time ends on the shipping paper for refrigerated liquefied gases transported in portable tanks. Knowing the holding time assists in preventing unexpected venting while in transportation, which could lead to exposure to a hazardous material release, and associated risks, as well as the loss of product. Including this information on the shipping paper aids in managing the transportation of refrigerated liquefied gases to ensure the material arrives safely at its destination without an unintended release of hazardous materials, including those that are known GHGs (*e.g.,* nitrous oxide). PHMSA anticipates that establishing this requirement to provide this information for portable tanks will improve safety and decrease climate change impacts of international transport of refrigerated liquefied gases in portable tanks. DGAC provided a comment in support of this revision.

Section 172.301

Section 172.301 prescribes general marking requirements for non-bulk packagings. PHMSA is amending paragraph (a)(1) to clarify that the exception permitting reduced size marking requirements are applicable to packages with either 5 L or less capacity, or those with a 5 kilograms (kg) or less net mass. The current HMR text states that the exception is applicable to packages with a maximum capacity of 5 kg or 5 L or less, rather than the maximum net mass, which is the more appropriate measure for

packages containing solids. A person shipping a solid material may unnecessarily apply the volume limitation when a net mass limit is intended. This revision clarifies that packages for solid material may have a maximum net mass of 5 kg or less. This editorial revision is intended to reduce confusion over the application of the exception at § 172.301(a)(1) in that for solid materials, the quantity limit is based on the net amount of solid material and not the capacity of the packaging the material is placed in. This clarification is consistent with similar provisions for solids (net mass) and liquids (capacity) throughout the HMR. Ensuring the appropriate application of the reduced size marking allowance provides consistency across persons using the reduced-size marking and therefore, is expected to improve safety of transport. PHMSA received a comment from DGAC in support of this revision.

Section 172.315

Section 172.315 prescribes the marking requirements for packages of limited quantities. Currently, the HMR require that the limited quantity mark be applied on at least one side or one end of the outer packaging. The 2021–2022 ICAO Technical Instructions clarified that marks, in particular those that are applied in a similar manner to self-adhesive labels, must be applied on one side of a package (*i.e.,* not folded over an edge). Prior to these amendments, only hazard communication labels were required to be applied to a single side of a package and prohibited from being folded around the edge of a package. This requirement was extended to markings to ensure visibility and to communicate hazard(s) to the greatest extent possible. Consistent with the ICAO Technical Instructions, PHMSA is adding a new paragraph (b)(3) to require that—for air transport—the entire limited quantity mark must appear on one side of the package. PHMSA received a comment from DGAC in support of this revision. For detail on the rationale for this requirement, *see* SECTION 172.406 of the Section-by-Section Review of Amendments.

Section 172.322

Section 172.322 prescribes the marking requirements for hazardous materials that are also marine pollutants. Consistent with revisions in Special Provision 441 and § 172.203(l)(1) discussed above, PHMSA is limiting the scope of hazardous materials which are marine pollutants, that are subject to this technical name marking requirement. Specifically, PHMSA applies the technical name marking to proper shipping names that have a ''G'' assigned in column (1) of the § 172.101 Hazardous Materials Table or have the text ''n.o.s.'' as part of the proper shipping name. PHMSA also adds language directing shippers using ''UN3077, Environmentally hazardous substance, solid, n.o.s.'' or ''UN3082, Environmentally hazardous substance, liquid, n.o.s.,'' to Special Provision 441 for additional requirements.

Section 172.406

Section 172.406 specifies the requirements for the placement of labels on a package. The 2021–2022 ICAO Technical Instructions clarified that marks, in particular those that are applied in a similar manner to self-adhesive labels, must be applied on one side of a package. The ICAO Technical Instructions have long required that all hazard communication labels not be folded (around the edge of a packages) and be applied to a single side. This requirement was introduced to ensure visibility and communicate hazard(s) to the greatest extent possible. In a working group session, the ICAO Dangerous Goods Panel agreed that extending this labeling requirement to marks was appropriate as marks, like labels, provide hazard communication. While PHMSA has not specifically prohibited extending labels onto other sides of packaging and allows the use of smaller labels to accommodate smaller packagings, PHMSA appreciates the need for readily visible hazard communication by air. Therefore, for the sake of harmonizing with the ICAO Technical Instructions, and to ensure visibility to communicate hazards to the greatest extent possible, PHMSA is adding specific restrictions on wrapping marks and labels for shipments that are transported by air.

During a review of the specific marking requirements that were added in the 2021–2022 ICAO Technical Instructions, PHMSA found that the HMR do not contain the same express limitation on ''folding'' a part of a label around the edges of a package such that the entirety of a label would have to be on a single side. PHMSA expects that adopting both the pre-existing ICAO single side requirement for labels, and the recent requirement that marks must be on a single side of a package will provide increased visibility of hazard communication on the smaller package types that are frequently used in air transport. These measures also reduce ambiguity for air operator employees conducting acceptance checks as to whether the package appropriately indicates the hazards without having to make a subjective determination.

Therefore, PHMSA is requiring in a new paragraph (a)(1)(iii), that for air transport, the entirety of a required label must be displayed on one side of a package. For cylindrical packages not containing a traditional side, the labels and/or package must be of such dimensions that a label would not overlap itself. In the case of cylindrical packages containing radioactive materials, which require two identical labels, these labels must be centered on opposite points of the circumference and must not overlap each other. If the dimensions of the package are such that two identical labels cannot be affixed without overlapping each other, one label is acceptable provided it does not overlap itself.

In addition, PHMSA adds requirements that marks must not be folded for: the limited quantity mark in § 172.315(b); the excepted quantity mark in § 173.4a(g); and the UN3373 Category B infectious substance mark in § 173.199(a). The ICAO Technical Instructions were also amended to require that the lithium battery handling mark be applied on a single side of a package; however, this is already prescribed in § 173.185(c)(3)(i), applicable to all modes of transport. Regarding the Category B infectious substance mark, the revision helps ensure that any packages containing COVID–19 materials have appropriate visibility and thus, ensure the safe transport of such materials.

Section 172.447

Section 172.447 prescribes specifications for labels used for lithium batteries. In this final rule, PHMSA removes and reserves paragraph (c), which contains an expired transitional exception allowing for continued use of labels in conformance with the requirements that had been in place on December 31, 2016, until December 31, 2018. Since December 31, 2018, has occurred, the continued use of an outdated label is no longer allowed.

C. Part 173

Section 173.4a

Part 173 contains general requirements for shippers regarding shipments and packagings. Section 173.4a prescribes transportation requirements for excepted packages. For consistency with the ICAO Technical Instructions, PHMSA is adding a new paragraph (g)(3) to require that—for air transport—the entire excepted quantity mark must be displayed on one side of the package. For detail on the rationale

for this requirement, *see* SECTION 172.406 of the ''V. Section-by-Section Review of Amendments'' for discussion of the requirement to display a mark on a single side.

Section 173.14

In subpart A of Part 173, PHMSA adds a new section—§ 173.14—to provide exceptions from the HMR for certain devices or equipment containing hazardous materials that are in actual use or which are intended for use during transport. Examples of such devices include cargo tracking devices and data loggers attached to, or placed in, packages, overpacks, containers, or load compartments. These items often contain component hazardous materials, such as lithium batteries or fuel cells, necessary to power the device or equipment. The exception provides clarity for these types of devices which are not offered into transportation as part of the consignment but instead accompany it to collect or disseminate information during transport. Eligibility for the exception is limited to equipment that meets conditional safety requirements. These include requirements that the component hazardous material—*e.g.,* lithium batteries—meet the applicable construction and test requirements specified in the HMR, and that the equipment can withstand the shocks and vibrations normally encountered during transport. The equipment must also be safe for use in different environmental conditions that it may be exposed to during transport such as temperature variations, inclement weather, and conditions in which explosive atmospheres caused by gases, vapors, mists, or air/dust mixtures may occur. The text—slightly modified from the NPRM language—also clarifies that the exception is not applicable when this type of equipment is itself offered as cargo such that normal HMR requirements pertaining to packaging, shipping papers, marking, and labeling apply.

This new section is consistent with provisions adopted in the UNMR and the IMDG Code. Additionally—in response to the ongoing global COVID–19 public health emergency—on December 31, 2020,[23] and February 23, 2021,[24] ICAO published addenda to the 2021–2022 Edition of the ICAO Technical Instructions to provide a limited exception for lithium battery-powered data loggers and cargo tracking devices to facilitate the transport and distribution of COVID–19 pharmaceuticals, including vaccines. Specifically, the 2021–2022 ICAO Technical Instructions except these devices from lithium battery marking and documentation requirements when transported by aircraft. Consequently, PHMSA is adopting exceptions in this section of the HMR to cover all modes of transportation for certain devices or equipment containing hazardous materials that are in actual use or which are intended for use during transport. However, the exceptions associated with aircraft transportation are limited to marking and documentation for lithium ion and lithium metal battery-powered devices or equipment that accompany shipments of COVID–19 pharmaceuticals, including vaccines.

PHMSA received comments from COSTHA, DGAC, MDTC, and PRBA expressing concerns over the new § 173.14. MDTC is concerned that § 173.14 as proposed is too limited and unnecessary. Additionally, DGAC, MDTC, and PRBA expressed concern that § 173.14 contradicts a letter of interpretation (LOI) that the industry has relied on for several years (*i.e.,* LOI Ref. No. 15–0040). MDTC believes that § 173.14 might impact significant types of battery-powered equipment including medical devices such as hearing aids, defibrillators, and implantable devices that cannot be switched off completely during transportation.

COSTHA believes that the language as proposed in the NPRM appropriately addresses the intent of the international standard language that these devices are part of the packaging and supports adopting the provisions as drafted. PRBA generally supports PHMSA's intent to add § 173.14 to the HMR to provide exceptions for certain devices or equipment (*e.g.,* cargo tracking devices) containing hazardous materials that are in actual use or are intended for use during transport.

In response to the comments from COSTHA, DGAC, MDTC, and PRBA, PHMSA confirms the intent of § 173.14 is not to capture those hazardous materials within equipment being offered for transportation as part of a consignment (*i.e.,* offered into commerce). This section does not apply to electronic devices (such as hearing aids that may always be powered on as part of their design) that are themselves being offered for transportation as cargo. Rather, these provisions are only applicable to devices containing hazardous materials that are in use to provide monitoring of packages during transit. Thus, in order to provide more clarification and better understanding of the intent of the section, PHMSA adds a paragraph (c) to clearly state that § 173.14 does not apply to hazardous materials with equipment that is itself shipped as cargo; rather, this exception only applies to equipment that incorporate a hazardous material as part of its operation such as data loggers used to track packages while in transit. Furthermore, PHMSA confirms that LOI Ref. No. 15–0040 remains valid and is not in conflict with this section.

Section 173.27

Section 173.27 provides the general requirements for transportation by aircraft. PHMSA is making a number of corrections and revisions as follows: (1) revise paragraph (c)(2) to clarify that all package types containing ''UN3082, Environmentally hazardous substance, liquid, n.o.s.'' are excepted from the pressure differential requirements and not only limited quantities; (2) revise paragraph (f) introductory text to clarify the inner packaging quantity limits prescribed in Table 1 and Table 2 apply to combination packages and not only to excepted quantity packages; (3) in paragraph (f)(3) Table 1 and Table 2 add inner package limits for certain Class 9 HMT entries consistent with the ICAO Technical Instructions; and (4) in Table 1 and Table 2 remove the ''no limit'' quantity limits and add them to the paragraph (f) introductory text for a clearer description of the requirement for materials authorized to exceed 220 L or 200 kg in accordance with columns (9A) and (9B) of the 172.101 table. Finally, the 2021–2022 edition of the ICAO Technical Instructions contains editorial corrections to exceptions for ''UN3082, Environmentally hazardous substance, liquid, n.o.s.'' from differential pressure testing requirements in Packing Instructions 964 and Y964 (limited quantity). When reviewing the clarifying editorial correction[25] to the ICAO exception, PHMSA found that although the same update is not needed in the HMR, the corresponding exceptions in § 173.27 are not consistent with those provided for in the latest version of Packing

[23] ICAO, Addendum No.1 to the 2021–2022 of the ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air (Dec. 31, 2020), *https://www.icao.int/safety/DangerousGoods/Addendum Corrigendum%20to%20the%20Technical%20Instructions/Doc%209284-2021-2022.AddendumNo1.en.pdf.*

[24] ICAO, Addendum No.2 to the 2021–2022 of the ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air (Feb. 23, 2021), *https://www.icao.int/safety/DangerousGoods/Addendum Corrigendum%20to%20the%20Technical%20Instructions/Doc%209284-2021-2022.AddendumNo2.en.pdf.*

[25] Report of the ICAO Working Group 19 (paragraph 3.2.11) (May, 2019), *https://www.icao.int/safety/DangerousGoods/WG19/DGPWG.19.WP.030.en.pdf.*

Instructions 964 and Y964. PHMSA is revising § 173.27 to correct this discrepancy and align with the updated version of the ICAO Technical Instructions.

In a previous final rule, HM–215K,[26] PHMSA revised § 173.27 to align with the amendments made to the 2011–2012 edition of the ICAO Technical Instructions. That earlier edition of the ICAO Technical Instructions had included exceptions applicable to ''UN3082'' from the pressure differential requirements in Packing Instructions 964 and Y964 for fully regulated and limited quantity packages. The exceptions were added because ''UN3082'' materials assigned to Class 9 do not meet the criteria for classification as any other hazard class or division and are classified as hazardous materials solely because of their risk to the environment (*i.e.,* they are not capable of posing a risk to health, safety, or property when transported by air). When this exception was added by the HM–215K rulemaking, the text was placed in paragraph (f)(2)(vii), thereby inadvertently narrowing the exception to limited quantity materials. In the 2011–2012 edition of the ICAO Technical Instructions that the HM–215K rulemaking intended to align with, the exception from the pressure differential requirements applied to both combination packagings in PI 964 and limited quantity packagings in PI Y964. Therefore, to eliminate this inadvertent minor error created in 2011, PHMSA amends paragraph (c)(2) to except shipments of ''UN3082, Environmentally hazardous substance, liquid, n.o.s.'' from the pressure differential packaging requirements applicable for transportation by aircraft. This revision aligns the pressure differential exceptions for ''UN3082'' material with those found in the ICAO Technical Instructions and excepts these shipments, in all authorized packaging types, from the pressure differential requirements in paragraph (c)(2).

Further, PHMSA amends paragraph (f), which specifies requirements for combination packagings intended for transportation aboard an aircraft. A combination packaging, for transport purposes, consists of one or more inner packagings secured in a non-bulk outer packaging. Paragraph (f)(3) contains Table 1 and Table 2 indicating the maximum net capacity allowed for the inner packagings of the combination packaging on passenger-carrying and cargo aircraft, respectively. PHMSA revises paragraph (f) by moving the references to Table 1 and Table 2 from paragraph (f)(1)—applicable to excepted quantities—to the paragraph (f) introductory text. The intent of this revision is to clarify that the inner packaging limits specified in paragraph (f)(3) Table 1 and Table 2 apply to all combination packages used to transport hazardous material by aircraft and not just to excepted packages (*i.e.,* packages for which exceptions from certain provisions are provided in the HMR). As it currently reads, the instruction for all combination packagings is imbedded in the paragraph (f)(1), which outlines provisions for excepted packages, thus making it appear that Tables 1 and 2 apply only to excepted packages. Correcting the reference in paragraph (f) provides regulatory clarity by properly aligning packaging limits in the HMR with the ICAO Technical Instructions.

Additionally, the first column of Tables 1 and 2 provides the maximum net quantity per package from Column (9A) of the HMT. PHMSA is replacing the rows in Tables 1 and 2, noting that there are no maximum net capacity limits for quantities greater than 220 L for liquids and greater than 200 kg for solids with an instruction in the revised paragraph (f) introductory text conveying the same information.

Finally, PHMSA discovered that for certain Class 9 (miscellaneous hazardous) materials, the authorized inner packaging limit in the ICAO Technical Instructions is greater than the limit currently allowed in Tables 1 and 2 at § 173.27(f)(3). Therefore, PHMSA is revising paragraph (f)(3), Table 1 and Table 2 to address this inconsistency with the ICAO Technical Instructions. Specifically, PHMSA is revising—for consistency with the inner packaging limits provided in Packing Instructions 956, 958, and 964 of the ICAO Technical Instructions—inner packaging net capacity limits for the following Class 9 materials:

- UN1841, Acetaldehyde ammonia
- UN1931, Zinc dithionite *or* Zinc hydrosulphite
- UN1941, Dibromodifluoromethane
- UN1990, Benzaldehyde
- UN2071, Ammonium nitrate fertilizers
- UN2216, Fish meal, stabilized *or* Fish scrap, stabilized
- UN2315, Polychlorinated biphenyls, liquid
- UN2590, Asbestos, chrysotile
- UN2969, Castor beans *or* Castor flake *or* Castor meal or Castor pomace
- UN3077, Environmentally hazardous substance, solid, n.o.s.
- UN3082, Environmentally hazardous substance, liquid, n.o.s.
- UN3151, Polyhalogenated biphenyls, liquid *or* Polyhalogenated terphenyls, liquid *or* Halogenated monomethyldiphenylmethanes, liquid
- UN3152, Polyhalogenated biphenyls, solid or Polyhalogenated terphenyls, solid *or* Halogenated monomethyldiphenylmethanes, solid
- UN3334, Aviation regulated liquid, n.o.s.
- UN3335, Aviation regulated solid, n.o.s.
- UN3432, Polychlorinated biphenyls, solid

These materials have a history of safe transport under less restrictive inner packaging limits in accordance with the ICAO Technical Instructions. The revisions offer shippers greater flexibility in packaging options to transport these materials without a degradation of safety.

Section 173.59

Section 173.59 provides informational descriptions of terms for explosives. PHMSA is amending the description of the term ''detonators'' to include a reference to electronic programmable detonators. Additionally, PHMSA is adding a separate term and description for ''Detonators, electronic *programmable for blasting.*'' These revisions correspond to the addition of the UN0511, UN0512, and UN0513 (Detonators, electronic *programmable for blasting*) to the HMT. PHMSA intends to distinguish between ''electronic detonators'' and ''electric detonators,'' as each has different design characteristics, by adding these new entries in the HMT and the editorial amendments in § 173.59. PHMSA expects this additional precision in shipping descriptions will provide a safety benefit. *See* § 172.101 of the ''V. Section-by-Section Review of Amendments'' for additional discussion on electric and electronic detonators.

Section 173.115

Section 173.115 outlines classification criteria for Class 2 (gas) materials. PHMSA is updating the version of ISO 10156:2010, ''*Gases and gas mixtures—Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets,*'' incorporated by reference in paragraph (k), which specifies how the oxidizing ability of a Division 2.2 (non-flammable) gas should be calculated. Currently the HMR incorporates by reference the 2010 edition of this ISO standard and its associated technical corrigendum in § 171.7. As part of ISO's regular periodic review of each standard, ISO standard

[26] 76 FR 3308 (Jan. 19, 2011).

10156:2010 was reviewed and updated and a new revised ISO 10156:2017 was published in September 2017. The 2017 edition supersedes and replaces ISO 10156:2010, which had been technically revised through ISO 10156:2010/Cor 1:2010. PHMSA updates the incorporation by reference of ISO 10156, to the 2017 edition. The updated document includes technical revisions pertaining to the flammability of gases and gas mixtures in air as well as a new calculation method for determining the lower flammability limit of gas mixtures. PHMSA reviewed the calculation method and agrees that it will assist shippers in properly classifying a Division 2.2 gas, without introducing any adverse safety risks. Therefore, PHMSA incorporates by reference ISO 10156:2017 in § 173.115(k).

Section 173.134

Section 173.134 provides classification criteria and exceptions for Division 6.2 infectious substances. PHMSA revises paragraph (a) to include references to ''UN3549, Medical Waste, Category A, Affecting Humans, *solid or* Medical Waste, Category A, Affecting Animals *only, solid*.'' Specifically, paragraphs (a)(1), (a)(1)(i), and (a)(5) are revised by including UN3549 among the list of UN numbers to use for description of an infectious substance. These revisions are consistent with the addition of this new hazardous materials description to the HMT.

Additionally, PHMSA removes the term rickettsiae from the list of types of microorganisms in paragraph (a)(1). Rickettsiae are a specific group of bacteria, and this specific type of bacteria is redundant because bacteria are already listed as a type of potential pathogenic microorganism.

Section 173.137

Section 173.137 prescribes the requirements for assigning a PG to Class 8 (corrosive) materials. The HMR requires offerors to classify Class 8 material and assign a PG based on tests conducted in accordance with the OECD Guidelines for the Testing of Chemicals. One of the tests currently authorized in the HMR is the 2015 OECD Guideline for the Testing of Chemicals ''*Test No. 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method*'' which may be used to determine that a material is not corrosive to human skin. PHMSA is incorporating by reference the 2016 version of OECD Guidelines for the Testing of Chemicals ''*Test No. 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method.*'' This document was updated to introduce sub-categorization for skin corrosion and adopted by the OECD in 2013 and further revised in 2014, 2015, and 2016, as Guidelines for the Testing of Chemicals ''*Test No. 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method.*'' According to the OECD, this updated test method permits subcategorization of corrosive chemicals into three categories: sub-category 1A and sub-category 1B/C, which correspond to PG I, PG II, and PG III, respectively. However, prior to the 2016 edition of the OECD Guidelines, the ability to clearly distinguish between PG II and PG III had previously never been formally evaluated or validated due to the lack of high-quality reference in vivo data against which to benchmark the in vitro results.

Changes to the UNMR were made because of the additional level of sub-categorization and differentiation that is possible using this updated test method. Accordingly, PHMSA is allowing corrosive materials that are tested using OECD Guidelines for the Testing of Chemicals *Test No. 431* to be assigned to PG II without further in vivo testing if the test method does not clearly distinguish between PG II or PG III. Since the packing group assignment indicates the required level of packaging according to the degree of danger presented by hazardous materials, this would relegate corrosive material that cannot be clearly distinguished between a medium danger PG II and a low danger PG III to be subject to the more conservative packaging requirement associated with PG II material unless additional testing is conducted. PHMSA anticipates that the use of the 2016 version of the OECD Guidelines for the Testing of Chemicals *Test No. 431* will benefit shippers of potential corrosives by clarifying corrosivity determinations or exclusions and eliminating excessive testing to distinguish between PG II and PG III.

The regulatory text also references OECD Guidelines for the Testing of Chemicals *Test No. 404, 430, and 435,* which are already approved for incorporation by reference in this section, and no change was made to these standards in this final rule.

Section 173.172

Section 173.172 specifies the eligibility conditions for exception from packaging requirements for certain fuel tanks used on aircraft hydraulic power units. PHMSA makes editorial revisions to these provisions to clarify packaging limits for the fuel tanks that power hydraulic power units. The fuel tanks addressed in this section are comprised of a primary containment for the fuel in the hydraulic power unit. The primary containment must consist of a welded aluminum bladder as well as an outer vessel, which is packed in non-combustible cushioning material in a strong, tightly-closed metal outer packaging. Currently, paragraphs (a) and (b) of this section state that the ''Maximum quantity of fuel per unit and package is 42 L (11 gallons).'' PHMSA is replacing the word ''unit'' in this sentence in paragraphs (a) and (b) with the words ''primary containment'' for consistency with the second sentence of each paragraph which states that the ''primary containment of the fuel within this vessel must consist of a welded aluminum bladder having a maximum internal volume of 46 L (12 gallons).'' These editorial revisions to clarify that the maximum quantity of fuel authorized applies to both the fuel within the vessel and completed package (primary containment) rather than the hydraulic power unit itself. This revision aligns the language for this packaging exception in the HMR with the language that was similarly amended in the 2021–2022 ICAO Technical Instructions and the 21st revised edition of the UNMR. This alignment provides clarity for packaging of certain fuel tanks and, as such, PHMSA does not expect this revision to adversely affect safety.

Section 173.181

Section 173.181 prescribes packaging requirements for liquid pyrophoric materials. Specifically, § 173.181 provides the requirements on closures for metal or glass receptacles when used as inner packagings—*i.e.,* receptacles—in combination packagings. The UNMR contain Packing Instruction P404 which includes provisions for resealing inner receptacles with threaded closures. Currently, § 173.181 does not include provisions for resealing of inner receptacles with threaded closures. The safety concern when resealing inner receptacles that contain liquid pyrophoric materials is that small amounts of residue may adhere to the threads and present a hazard upon closing of the inner packaging and that friction generated from screwing the cap back onto the receptacle may cause the residue to react critically (*e.g.,* self-heating or spontaneous combustion). Based on this concern, the UNMR now permit closures of inner receptacles to be either threaded or physically held in place by any means capable of preventing back-off or loosening of the closure under conditions normally incident to transportation (*e.g.,* vibration

during transport). PHMSA is also concerned about this potential hazard and authorizes an alternative method of closure to prevent this potential hazard. Therefore, PHMSA revises the requirements of § 173.181 for closures of inner packagings for liquid pyrophoric materials to specify that they may have alternative closures that are physically held in place by any means capable of preventing back-off or loosening during transportation.

Section 173.185

Section 173.185 prescribes requirements for transportation of lithium cells and batteries. Paragraph (c) prescribes requirements for smaller cells or batteries and paragraph (c)(3) specifies hazard communication requirements including the use of the lithium battery mark. PHMSA revises the minimum size of the lithium battery mark from 120 millimeters (mm) wide by 110 mm high to 100 mm by 100 mm. This reduction in size requirements for this mark is consistent with the existing minimum size requirements for the limited quantity and excepted quantity marks in the HMR (*see* §§ 172.315 and 173.4a) and does not diminish the ability to read or recognize the marking. The reference to the shape of the mark is amended to include ''square'' to account for the new minimum dimensions while also maintaining the existing shape of a ''rectangle'' to continue authorized use of the lithium battery mark with 120 mm by 110 mm dimensions. In addition, the minimum size of the lithium battery mark for packages too small to display the revised 100 mm by 100 mm dimensions, is revised from 105 mm wide by 74 mm high to 100 mm wide by 70 mm high. Additionally, an informal working paper [27] submitted to the 54th Session of the UNSCOE noted that due to the large volume of lithium batteries shipped in small packages, the reduction in the size of the mark could reduce the quantity of packagings produced and consequently the quantity of empty packagings sent for disposal or recycling. This minimum size does not invalidate use of larger marks meeting the currently authorized minimum size requirements.

COSTHA, DGAC and MDTC provided comments in support of this revision. COSTHA notes that while some of its members are in favor of adopting new size requirements for the lithium battery mark, other members are concerned about reducing the size of hazard communication on packages. Moving forward, COSTHA requests that PHMSA continue to consider the impact of reducing hazard communication (by size or example) and be open to alternate forms of hazard communication that may be more effective for both carriers/operators and emergency responders. PHMSA acknowledges the comments and concerns raised by some COSTHA members on the new minimum size requirements for lithium battery markings. However, PHMSA understands that the minimal reduction (no more than 5 mm in each direction) in required size for markings adopted in this final rule will not cause a reduction in safety.

Section 173.187

Section 173.187 prescribes packaging requirements and other provisions for ''pyrophoric solids, metals, or alloys, n.o.s.'' The 21st revised edition of the UNMR includes an amendment to Packing Instruction P404 to address concerns with threaded closures when resealing inner receptacles after partial removal of product. The amendment addresses small amounts of residue of pyrophoric materials that may adhere to the threads and present a hazard upon closing of an inner receptacle. As with liquid pyrophoric materials discussed above, there is concern that friction generated from screwing the cap back onto the inner receptacle may cause the residue to react critically (*e.g.,* self-heating or spontaneous combustion). Based on this concern, the UNMR now allow closures of inner receptacles to be either threaded *or* physically held in place by a means capable of preventing back-off or loosening of the closure under conditions normally incident to transportation (*i.e.,* impact or vibration during transport).

After reviewing this issue, PHMSA is also concerned about this potential hazard and amends § 173.187 to authorize an alternate method of closure to prevent this potential hazard. Specifically, PHMSA is revising the requirements for closures of inner receptacles for solid pyrophoric materials to specify that they may have threaded closures or other alternative closures that are physically held in place by a means capable of preventing back-off or loosening.

Section 173.199

Section 173.199 prescribes the packaging requirements for Division 6.2 Category B infectious substances. Consistent with the ICAO Technical Instructions, PHMSA is revising paragraph (a)(5) to require that for air transport the entire ''UN3373'' mark must appear on one side of the package. PHMSA expects that placing marks on a single side of a package will provide increased visibility of hazard communication on the smaller package types that are frequently used in air transport. These measures also reduce ambiguity for air operator employees conducting acceptance checks as to whether the package appropriately indicates the hazards without having to make a subjective determination. Regarding the Category B infectious substance mark, the revision helps ensure that any packages containing infectious substances, including COVID–19 materials, have appropriate visibility and thus, ensure the safe transport of such materials. For details on the rationale for this requirement, *see* the discussion of § 172.406 in the ''V. Section-by-Section Review of Amendments.''

Section 173.218

Section 173.218 contains packaging and product stabilization requirements for transporting stabilized fish meal or fish scrap (UN2216) as a Class 9 material. Currently, the provisions of this section are limited to shipments by vessel; however, PHMSA amends this provision to authorize the transport of this material by air. This revision responds to changes in the fish meal or fish scrap market which has experienced an increased demand for more timely shipments of samples of this item for evaluation by potential purchasers. Adding provisions to permit shipment by air, rather than limiting to shipment by vessel, relieves frustration in the market for fish meal or fish scrap by allowing shipments of small amounts of this material to be expedited by air. This revision is consistent with amendments adopted in the 2021–2022 version of the ICAO Technical Instructions, which have been revised to allow the transport by air of non-bulk packages of fish meal or fish scrap, subject to quantity limitations and stabilization requirements.

Under this revision, UN2216 material is permitted on passenger aircraft and cargo aircraft in amounts up to 100 kg and 200 kg, respectively, and in UN performance packaging that aligns with the ICAO Technical Instructions. Additionally, to ensure the safe transport of this material by air, PHMSA is adding stabilization requirements similar to those that are in place for shipments by vessel. Stabilization of

[27] Rechargeable Battery Association (PRBA) & the Advanced Rechargeable & Lithium Batteries Association (RECHARGE), Proposal on the Dimensions of the Lithium Battery Mark Submitted to the UN Subcommittee of Experts on the Transport of Dangerous Goods at the 54th Session (Dec. 3, 2018), *https://www.unece.org/fileadmin/DAM/trans/doc/2018/dgac10c3/UN-SCETDG-54-INF55.e.pdf.*

fish meal and fish scrap by applying antioxidants is required in order to offer the material under a Class 9 stabilized proper shipping name. The stabilization of fish meal and fish scrap is needed in order to mitigate a fire hazard while in transportation. Fish meal or fish scrap transported by air must have been stabilized at production, and within the twelve months prior to transportation. Given the safeguard provided by stabilization of this material prior to transportation, as well as the packaging and quantity restrictions, PHMSA expects that there will be no degradation of transportation safety in authorizing air transportation.

In addition to adding these stabilization requirements for air transportation, PHMSA amends the stabilization requirements that are currently in place for vessel shipments. The HMR currently requires shipments of fish meal or fish scrap by vessel to contain at least 50 parts per million (ppm) (mg/kg) of ethoxyquin, 100 ppm (mg/kg) of butylated hydroxytoluene (BHT), or 250 ppm (mg/kg) of tocopherol-based antioxidant at the time of shipment for bulk shipments when transported in freight containers. PHMSA extends these stabilization requirements to all vessel shipments, as required by the IMDG Code. While the change in language makes the stabilization requirement more widely applicable, PHMSA expects that the impact on the regulated community will be minimal as fishmeal and fish scrap shipments offered for transport (in non-bulk and bulk) are already typically treated with quantities of stabilizer (antioxidants) well above the minimum amounts currently shown in section § 173.218 as common industry practice.

Section 173.221

Section 173.221 prescribes transportation requirements and exceptions for ''UN2211, Polymeric beads expandable'' and ''UN3314, Plastic molding compound,'' which are both Class 9 (miscellaneous) materials. Historically, transportation of these materials has been limited to single packagings under both the HMR and in Packing Instruction 957 of the ICAO Technical Instructions. However, these limitations are inconsistent with the UNMR and the general provisions of the ICAO Technical Instructions, which permit combination packagings when single packagings are authorized. These packagings are constructed with inner packagings made of glass, plastic, metal, paper, or fiber and with outer packagings utilizing drums, boxes, and jerricans made of various materials. This conflict in permitted packagings has been corrected in the most recent edition of the ICAO Technical Instructions.

PHMSA finds that allowing combination packaging for these Class 9, low hazard materials is consistent with general packaging authorizations throughout the HMR. In general, combination packaging is allowed for materials that are more hazardous as long as the minimum packaging performance requirements are achieved. Single packaging and combination packaging are subject to the same performance standards, meaning an equivalent level of safety is achieved. Therefore, PHMSA is making conforming revisions to § 173.221 to allow the use of combination packagings (*i.e.,* packagings that use a combination of inner and outer packagings for containment) for these materials. This revision provides packaging selection flexibility as well as consistency with UNMR and revised ICAO Technical Instructions without any impact on safe transport of these materials. DGAC provided a comment in support of this revision.

Section 173.222

Section 173.222 specifies the non-bulk packaging requirements for ''UN3363, Dangerous goods in machinery or apparatus.'' As discussed in revisions to § 172.101, PHMSA is modifying the proper shipping name associated with UN3363 to include ''dangerous goods in articles,'' in addition to ''dangerous goods in machinery or apparatus.'' In the HM–215O final rule, PHMSA added new entries for articles containing hazardous materials that are not otherwise specified by name in the HMT (*e.g.,* ''UN3547, Articles containing corrosive substance, n.o.s.''). These new entries addressed transportation scenarios where various hazardous materials or residues are present in articles above the quantities currently authorized for machinery or apparatus transported as ''UN3363, Dangerous goods in machinery *or* Dangerous goods in apparatus.'' In addition to adding these new entries to the HMT, PHMSA added packaging provisions in § 173.232, as well as a definition for articles. The definition states that ''article means machinery, apparatus, or other devices containing one or more hazardous materials (or residues thereof) that are an integral element of the article, necessary for its functioning, and that cannot be removed for the purpose of transport.'' This addition created regulatory discrepancies between articles that cannot be defined as machinery or apparatus but also do not qualify as ''Articles containing hazardous materials, n.o.s.'' even as there is no safety basis to exclude such articles from the scope of § 173.222 provisions. Therefore, PHMSA revises the provisions in § 173.222 to reflect the addition of dangerous goods in articles to the current HMT entry for ''UN3363, Dangerous Goods in Machinery *or* Dangerous Goods in Apparatus'' as discussed in connection with the revisions to § 172.101 above. These revisions are intended to provide flexibility in the choice of the most appropriate modifier to be selected as a proper shipping name (*e.g.,* article, machinery, or apparatus). This flexibility in selecting the most appropriate description of the hazardous material helps ensure appropriate packaging selection and hazard communication, thus enhancing safety.

Section 173.225

Section 173.225 prescribes packaging requirements and other provisions for organic peroxides. As a result of new peroxide formulations becoming commercially available, the 21st revised edition of the UNMR includes updates to the list of identified organic peroxides and new packing instructions for these materials. To maintain consistency with the UNMR, PHMSA is updating the Organic Peroxide Table in § 173.225(c) to revise the entry ''Di-(4-tert-butylcyclohexyl) peroxydicarbonate [as a paste],'' by (1) changing the classification of the material as ''UN3116, Organic peroxide type D, solid, temperature controlled'' to ''UN3118, Organic peroxide type E, solid, temperature controlled''; and (2) changing the packing method from OP7 to OP8.

An organic peroxide Type D is an organic peroxide that: (1) detonates only partially, but does not deflagrate rapidly and is not affected by heat when confined; (2) does not detonate, deflagrates slowly, and shows no violent effect if heated when confined; or (3) does not detonate or deflagrate, and shows a medium effect when heated under confinement. An organic peroxide Type E is an organic peroxide which neither detonates nor deflagrates and shows low or no effect when heated under confinement. Di-(4-tert-butylcyclohexyl) peroxydicarbonate was identified as a Type E organic peroxide based on evaluation of new test data within the classification scheme for self-reactives and organic peroxide in Figure 20.1 of the UNMR. Finally, PHMSA revises the packing method from OP7 to OP8 consistent with the revised classification of Di-(4-tert-

butylcyclohexyl) peroxydicarbonate to a lesser hazard Type E organic peroxide. The packaging method indicates the largest size authorized for packaging of a particular organic peroxide. Specifically, for Di-(4-tert-butylcyclohexyl) peroxydicarbonate, assignment of OP8 allows up to 400 kg for solids and combination packagings, and up to 225 L for liquids.

PHMSA revises the Organic Peroxide IBC Table in paragraph (e) to maintain alignment with the 21st revised edition of UNMR by adding new entries for ''tert-Amyl peroxypivalate, not more than 42% as a stable dispersion in water'' and ''tert-Butyl peroxypivalate, not more than 42% in a diluent type A'' and identifying it as ''UN3119, Organic peroxide type F, liquid, temperature controlled.'' PHMSA determines that adding provisions for the transport of these newly available peroxide formulations will allow better oversight for safe and consistent shipment of these hazardous materials.

Section 173.301b

Section 173.301b outlines additional general requirements when shipping gases in UN pressure receptacles (*e.g.,* cylinders). Paragraph (a)(2) of this section requires that the gases or gas mixtures be compatible with the UN pressure receptacle and valve materials prescribed for metallic materials in ISO 11114–1:2012(E), *Gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 1: Metallic materials.* This document provides compatibility requirements for the selection of combinations of metallic cylinder and valve materials for use with gas or gas mixtures. In the interest of providing uniformity with regard to reference standards used domestically and internationally, PHMSA is revising the compatibility requirements to include a reference to the 2017 amendment (ISO 11114–1:2012/Amd 2017(E)), which ISO published as a supplement to ISO 11114–1:2012(E). This amendment provides enhanced instructions on the permissible concentrations of certain gases to ensure safe transport of a wider variety of gases in newly developed types of metallic cylinders and valves.

Second, PHMSA revises paragraph (c)(1), which specifies valve requirements for pressure receptacles. Currently in the HMR, paragraph (c)(1) requires valves for pressure receptacles (excluding quick release cylinder valves, which must conform to the requirements in ISO 17871:2015(E)) to conform to various editions of ISO 10297, ''*Gas cylinders—Cylinder valves—Specification and type testing*'', including the 1999, 2006, and 2014 editions. ISO 10297:2014 specifies design, type testing, and marking requirements for certain cylinder valves intended to be fitted to refillable transportable gas cylinders which convey compressed, liquefied, or dissolved gases. PHMSA is modifying the valve requirements in this paragraph such that when the use of a valve is prescribed, the valve must conform to the requirements of ISO 10297:2014 as well as the supplemental amendment, ISO 10297:2014/Amd 1:2017. ISO 10297:2014/Amd 1:2017(E) corrects errors in ISO 10297:2014 and also includes modifications for valves for tubes and pressure drums. For consistency with the UNMR, PHMSA also adds a sunset date of December 31, 2022, for the authorization of the use of ISO 10297:2014 when not used in conjunction with the supplemental 2017 amendment. PHMSA has reviewed this supplemental amendment as part of its regular participation in the review of amendments for the UNMR and does not expect any degradation of safety standards in association with the use of these two documents.

Lastly, paragraph (c)(2) of this section outlines certain requirements for valves on UN pressure receptacles. Specifically, by following one of the listed methods or standards in this paragraph, valves are required to be protected from damage that could cause inadvertent release of their contents. PHMSA is introducing an additional option by allowing the use of valves designed and constructed in accordance with Annex A of ISO 17879:2017 for UN pressure receptacles with self-closing valves with inherent protection (except those in acetylene service). Annex A of ISO 17879:2017 is a new standard which establishes design, type testing, marking, and manufacturing tests and examination requirements for self-closing valves fitted to refillable transportable gas cylinders conveying compressed, liquefied, or dissolved gases (other than acetylene). PHMSA has determined that incorporating ISO 17879 fulfills the need for a standard that governs self-closing valves on cylinders, which are typically used in the calibration, beverage, and medical gas industries and mirrors requirements for impact testing and burst testing specified in ISO 10297. PHMSA has experience with permitting the use of valves constructed to ISO 17879 through special permit,[28] which has occurred without incident since 2019. Incorporating this ISO standard eliminates the need and associated burden for manufacturers to request a special permit to use the valves as they become more widely transported as a result of their authorization by other competent authorities.

The regulatory text references the following standards that are already approved for incorporation by reference in this section and no revisions are being made to these standards: ISO 11114–1:2012(E); ISO 11114–2:2013; ISO 10297:2014; ISO 17871:2015; ISO 11117:2008 and Technical Corrigendum 1; ISO 11117:1998; ISO 16111:2008.

Section 173.304b

Section 173.304b contains additional requirements for shipment of liquefied compressed gases in UN pressure receptacles. In this section, paragraph (b) describes the filling limits for UN pressure receptacles expressed in terms of ''filling ratio,'' or the ratio of the mass of gas in the cylinder compared to the water capacity of the cylinder. Paragraph (b)(2) of this section provides the maximum allowable filling limits for low pressure liquefied gases. As currently provided in paragraph (b) of 173.304b, the term ''filling factor'' is currently used to describe the filling limit in terms of the maximum mass of contents in kg of the gas per liter of water capacity, which is intended to have the same meaning as the ''filling ratio.'' To increase clarity of the HMR, PHMSA revises paragraph (b)(2) by deleting the term ''filling factor'' and only using the performance standard of ''maximum mass in kilograms of contents per liter of water capacity'' so that this is not misunderstood as being different from the defined term ''filling ratio.'' This revision is consistent with the same editorial correction made in the 21st revised edition of the UNMR. The term ''filling factor'' is used in the context of the UNMR and could be misunderstood as being different from the defined term ''filling ratio.'' Clarifying the language pertaining to the filling ratio will provide a safety benefit by eliminating confusion about the definition of the term ''filing factor'' or ''filing ratio.''

Section 173.306

Section 173.306 provides exceptions from HMR requirements for transportation of limited quantities of compressed gases. Paragraph (f) of this section provides exceptions for the transportation of accumulators, which are transported under ''UN3164, Articles, pressurized pneumatic *or* hydraulic.'' Accumulators are devices in

[28] See, *e.g.,* Special Permit 20876 (Apr. 21, 2021), *https://cms7.phmsa.dot.gov/approvals-and-permits/hazmat/file-serve/authorization/2019045387_SP20876.pdf/2019045387/SP20876.*

which a fluid is kept under pressure as a means of storing energy. PHMSA revises paragraphs (f)(2) and (f)(3) to allow robust accumulators to be transported unpackaged, in crates, or in overpacks that provide equivalent protection to the hazardous material being transported. The term robust is used to describe articles that are strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between cargo transport units and between cargo transport units and warehouses, as well as any removal from a pallet for subsequent manual or mechanical handling. PHMSA expects that the amendments will increase flexibility for shippers and harmonize with revisions to the UNMR which limits the packaging required for ''UN3164, Articles, pressurized pneumatic *or* hydraulic'' when afforded equivalent protection by the article being transported.

Additionally, PHMSA adds a new paragraph (n) to include provisions for the transport of ''UN2037, Receptacles, small, containing gas *or* gas cartridges'' for recycling or disposal. These provisions include packaging requirements, conditions for exception, and maximum gross weight limits, applicable to small receptacles or cartridges containing gas not exceeding 1.0 L (0.3 gallons) capacity. Codifying these provisions will create a regulatory framework for transporting these materials for recycling or disposal and reduce the administrative burden that otherwise applies to fully regulated gas receptacles. Further, reducing this administrative burden may lead to other environmental benefits by facilitating shipments destined for recycling or disposal.

Section 173.335

Section 173.335 specifies packaging requirements for hazardous materials transported as chemicals under pressure (*e.g.,* ''UN3500, Chemical under pressure, n.o.s.''). Chemicals under pressure are regulated as gases but differ in that they are liquids, pastes, or powders, and pressurized with a propellant that meets the definition of a gas in § 173.115. Materials transported under ''UN3500'' may include those that are widely used in fire suppression systems and other items used for fire control.

PHMSA is providing an extended periodic inspection period for cylinders containing fire extinguishing agents transported under UN3500. This amendment is consistent with a new special packing provision—PP97—added in the 21st revised edition of the UNMR to provide a test period of 10 years for tubes (cylinders) that have a capacity of 450 L or less and that are filled with fire extinguishing agents. The intent of this revision was to resolve the discrepancy in inspection periods between (1) gas-filled cylinders intended for installation in fire suppression systems and (2) cylinders used for the same purpose, but which contain a fire extinguishing agent (*e.g.,* a liquid) in combination with a gas used as a propellant. Gases transported under ''UN1956, compressed gas n.o.s.'' have a maximum test period for periodic inspection of 10 years, whereas the maximum test period for ''UN3500, chemical under pressure, n.o.s.'' is only five years. However, the updated UNMR extended the inspection period for cylinders containing fire extinguishing agents transported under UN3500 because they are typically (1) inert chemicals with no subsidiary risks and (2) they are typically filled at lower pressures than cylinders containing UN1956 materials. Additionally, these fire extinguishing materials and devices are maintained and stored in a manner that minimizes the degradation of the cylinder (*e.g.,* in protected indoor environments).

A recent PHMSA rulemaking, HM–234,[29] broadened the scope of cylinders eligible to be classified as ''UN1044, fire extinguishers'' and the intent was to permit cylinders charged with fire extinguishing agents intended for use in fire suppression systems to be described and transported under ''UN1044, fire extinguishers.'' However, cylinders charged solely with a compressed gas or liquefied gas and used in a fire suppression system solely to expel a separately stored extinguishing agent are not eligible for transportation under UN1044. Furthermore, with respect to the UNMR, cylinders charged with a fire extinguishing agent and intended for use in a fire suppression system are specifically excluded from transportation as ''UN1044, fire extinguisher.'' Therefore, while HM–234 added provisions that may allow hazardous materials in cylinders that have historically been described and transported as UN1956 or UN3500 to be transported as ''UN1044, fire extinguisher'', amending § 173.335 is still necessary to maintain alignment with the UNMR because the UNMR still do not allow cylinders intended for use in fire suppression systems to be transported under UN1044.

Because of this conflict in classification for similar items, PHMSA extends the periodic inspection period for cylinders containing gases or liquid/gas mixtures that are used as fire extinguishing agents under UN3500, to facilitate international shipment of these items by aligning the § 173.335 periodic inspection requirements with the periodic inspection period adopted in the UNMR. Recognizing that these items UN3500 and UN1044 are functionally the same but classified differently outside of the United States, PHMSA expects that establishing parallel inspections periods for similar items will facilitate international movement and continued use of these cylinders domestically and internationally. DGAC provided comments in support of this revision. Additionally, DGAC requests that PHMSA consider expanding the retest period for cylinders that are used for other hazard classes, such as flammable liquids, that are not transported under pressures meeting the definition of a compressed gas. PHMSA appreciates DGAC's comment; however, expanding the retest period for cylinders containing other hazardous classes is beyond the scope of this rulemaking and would benefit from stakeholder input in a future rulemaking. PHMSA encourages DGAC to consider submitting a petition for rulemaking in accordance with § 106.100 providing data and justification for why PHMSA should expand the cylinder retest period when used in service for hazardous materials other than gas.

D. Part 175

Section 175.8

Part 175 prescribes requirements that apply to the transportation of hazardous materials in commerce aboard aircraft, including items carried by air passengers and crew, as well as items carried by the aircraft operator in accordance with airworthiness requirements and operating regulations, or in support of in-flight service. Section 175.8 provides exceptions from the HMR for certain equipment and materials used by aircraft operators that are regulated as hazardous materials. PHMSA amends paragraph (b) to provide a new exception for alcohol-based hand sanitizers and alcohol-based cleaning products carried aboard an aircraft by the operator for the purposes of passenger and crew hygiene. These changes align the HMR with amendments made to the ICAO Technical Instructions—as amended in Addendum 1—published on December 31, 2020, in response to the COVID–19 public health emergency. The intent of this amendment is to ensure that air operators are able to equip aircraft with

[29] 85 FR 85380 (Dec. 28, 2020).

alcohol-based sanitizers for use in the cabin for the purposes of passenger and crew hygiene without the regulatory burden of documentation and packaging otherwise associated with the transport of Class 3 (flammable liquid) hazardous materials. Finally, in this final rule, we are adjusting the regulatory text slightly from what was proposed in the NPRM to clarify that the alcohol-based hand sanitizers and alcohol-based cleaning products should be physically in the cabin of the aircraft. We expect that this minor modification captures the true intent of this exception more accurately. This amendment is beneficial to public interest given that it assists in limiting the spread and contraction of viruses such as COVID–19 without an anticipated decrease in transportation safety.

Section 175.9

Section 175.9 provides exceptions for certain special aircraft operations. Paragraph (b)(5) excepts organ preservation units necessary to protect human organs when carried in the aircraft cabin, provided certain conditions are met. As written, the current provisions only allow for devices powered by non-spillable batteries. However, the technology for powering such devices has evolved to include lithium batteries. To maintain consistency with the ICAO Technical Instructions, PHMSA adds provisions for organ preservation units powered by lithium batteries (both metal and ion). Specifically, lithium metal or lithium ion cells or batteries must meet the general provisions prescribed in § 173.185(a) and spare lithium batteries need to be individually protected to prevent short circuits when not in use to ensure safe transport. PHMSA expects this amendment will promote broader use of the exception for organ preservation units. Finally, it facilitates international movement of these devices by harmonizing with ICAO Technical Instructions which allow lithium batteries as power sources for the devices while still ensuring safe transport.

Section 175.10

Section 175.10 specifies the conditions under which passengers, crew members, or an operator may carry hazardous materials aboard a passenger aircraft. PHMSA amends paragraph (a)(1)(ii) of this section to permit Division 2.2 aerosols with no subsidiary hazard, in addition to those that are not for medicinal or personal toiletry use, as carry-on items (*see* § 175.10(a)(1)(i) for provisions pertaining to non-radioactive medicinal and toilet articles). Currently, these materials (*i.e.,* Division 2.2 non-flammable gases) are only authorized in checked baggage. Additionally, PHMSA is adding a conditional requirement to new paragraph (a)(1)(iv) that the material in the Division 2.2 aerosols must not cause extreme annoyance or discomfort, in the event of an unintentional release, to crew members so as to inhibit performance of their assigned duties. The revisions align the HMR with amendments made to the ICAO Technical Instructions. In addition, these revisions are consistent with special permit DOT–SP 21021,[30] which was issued in response to the COVID–19 public health emergency to ensure flight crews could carry-on sanitizing aerosol products that may not have been considered as items for personal use. PHMSA has determined that this revision is beneficial and in the public interest because it expands the use of the passenger and crewmember exceptions applicable to Division 2.2 aerosols by allowing such aerosols in carry-on baggage. This is particularly beneficial for sanitizers to aid in preventing the potential spread and contraction of viruses such as COVID–19 without an anticipated decrease in transportation safety.[31]

Section 175.10(a)(11) outlines the provisions for self-inflating personal safety devices and currently allows for the carriage of only one device with the approval of the aircraft operator. PHMSA is increasing the allowance from a single self-inflating personal safety device to two devices in response to an increase in passengers seeking to travel with their own devices. PHMSA clarifies that each self-inflating safety device may be fitted with no more than two small gas cartridges and that an additional two spare cartridges per device may be carried with the devices. In addition, PHMSA adds the text ''intended to be worn by a person'' to specify that this provision is only intended for self-inflating personal safety devices that are designed to be worn by a person and does not apply to other types of safety devices. PHMSA expects this revision will promote use of the self-inflating personal safety devices. Specifically, it provides passengers more flexibility when carrying self-inflating devices such as lifejackets, motorcycle jackets, and horse-riding vests. Further, PHMSA does not expect transportation safety will be compromised as these devices are designed with multiple initiation processes required for inflation to occur, thereby inhibiting unintentional activation. PHMSA has not identified any incidents involving unintentional activation of self-inflating personal safety devices inflight.

Section 175.75

Section 175.75 provides quantity limitations and stowage location requirements for air transportation. During internal review of the stowage requirements found in § 175.75, PHMSA and FAA concluded that making several editorial revisions increases the clarity of this section, and therefore would enhance the safety of hazardous materials transported by aircraft. These revisions do not substantively change current requirements of this section and they are intended only for purposes of increasing the understanding of air stowage requirements. The editorial revisions to this section are discussed as follows:

- The current structure for paragraph (b) outlines three distinct stowage requirements in a single paragraph. To increase readability, PHMSA revises paragraph (b) by separating the three requirements into three subparagraphs each addressing a single stowage requirement. In response to the NPRM, PHMSA received a comment from Airbus suggesting that PHMSA also include reference to a Class F compartment in § 175.75(b). However, this comment is beyond the scope of this rulemaking since PHMSA did not propose to include requirements associated with Class F cargo compartments in the NPRM, and therefore, is not included in this final rule. Additionally, PHMSA encourages Airbus to submit a petition for rulemaking in accordance with § 106.100 providing data and arguments for why Class F cargo compartments should be included in § 175.75(b).
- Insertion of an additional distinct sentence in the aforementioned revised format of paragraph (b) to highlight the existing requirement in § 175.75 that all packages displaying a ''Cargo Aircraft Only'' label in accordance with § 172.402(c) must be loaded in an accessible manner (*i.e.,* a manner accessible to the cargo aircraft's crew or other authorized person). This longstanding requirement of the HMR is buried in the Quantity and Loading Table of paragraph (f). In the past, air carrier stakeholders have suggested to PHMSA and FAA that the stowage

[30] DOT Special Permit 21021 (May 29, 2020), *https://www.phmsa.dot.gov/approvals-and-permits/hazmat/file-serve/offer/SP21021.pdf/2020034999/SP21021.*

[31] PHMSA notes that, apart from the revisions to § 175.10 of the HMR proposed here, transportation of aerosols in carry-on baggage and for any other purpose may be subject to limitations imposed by other regulators, including (but not limited to) the Transportation Security Administration.

requirements would be clearer if this important requirement were explicitly stated in § 175.75. Therefore, PHMSA is specifying this requirement in the stowage requirements as new subparagraph (b)(4).

• Correction of an inadvertent error in the Quantity and Loading Table of paragraph (f), Note 1, that removed Division 6.2 material from eligibility for exception from the inaccessible loading restriction for Cargo Aircraft Only packages. This inadvertent error occurred in a corrections and response to administrative appeals final rule.[32] PHMSA revised requirements for Division 6.1 material among the list of eligible materials but in doing so inadvertently removed reference to Division 6.2 material. This change was not intended and therefore, PHMSA is reinserting reference to Division 6.2 material in Note 1.

• Insertion of an Oxford comma in the Quantity and Loading Table of paragraph (f), Note 1, item d. to more clearly indicate that Class 9 material, limited quantity material, and excepted quantity material all qualify for this provision. PHMSA and FAA are aware that some air carrier stakeholders have expressed confusion with the language in Note 1, item d., and acknowledge that the omission of a comma between ''Limited Quantity'' and ''Excepted Quantity'' may create the impression that only Class 9 limited or excepted quantity material are eligible for this exception. Note 1, item d. has always included all eligible hazard classes of limited quantity and excepted quantity material.

E. Part 176

Section 176.84

Part 176 contains requirements associated with transportation of hazardous materials by vessel. Section 176.84 prescribes the meanings of numbered or alphanumeric vessel transport stowage provisions that are assigned to hazardous materials, and which are listed in column (10B) of the HMT. The provisions in § 176.84 are separated into general stowage provisions, which are defined in the ''table of provisions'' in paragraph (b), and the stowage notes unique to vessel shipments of Class 1 explosives, which are defined in the table in paragraph (c)(2). PHMSA has determined that the following revisions will improve safety by ensuring that hazardous materials are properly stowed on vessels.

First, PHMSA is revising stowage provision 4 in paragraph (b). Existing stowage provision 4 directs shippers to ''Stow 'Separated from' liquid organic materials.'' PHMSA modifies the language in this code for clarity and to facilitate proper stowage. In a proposal submitted to the IMO, it was noted that many liquid organic materials are not dangerous goods and that it is difficult to identify these commodities for purposes of segregation.[33] Furthermore, the distinction between organic and inorganic substances cannot be easily discovered by persons responsible for packing a cargo transport unit. PHMSA has determined that requiring a determination as to whether a cargo is an organic or inorganic substance should be amended with a more readily understood requirement to characterize these items as combustible materials. This clarification aids in ensuring safe segregation of materials assigned this stowage provision. Therefore, PHMSA is amending stowage provision 4 to require materials assigned this code to ''not be stowed'' with combustible materials in the same cargo transport unit.

Second, PHMSA adds new stowage provisions under codes 155, 156, and 157:

• New stowage code 155 is assigned to ''UN2814, Infectious substances, affecting humans'' and ''UN2900, Infectious substances, affecting animals only.'' This new stowage provision advises vessel carriers to avoid handling of an infectious package or keep handling of the package to a minimum and to inform the appropriate public health authority or veterinary authority where persons or animals may have been exposed to the package contents. This provision may improve safety for packages that may be used to transport COVID–19 related material. Stowage code 155 applies particularly to any cargo offered in the traditional manner (*i.e.,* break-bulk). The stowage code advises cargo handling personnel to limit interaction with packages of Division 6.2 materials to a minimum. The requirement to notify the appropriate public health authority or veterinary authority where persons or animals may have been exposed to package contents is intended to ensure appropriate medical attention can be provided in the event of an exposure and to control any potential further contamination as a result of contact with the material. This new stowage code serves to ensure vessel carriers are aware of the potential hazard of these packages and to ensure they follow all protocols related to handling such packages.

• New stowage code 156 is assigned to ''UN3090, Lithium metal batteries,'' ''UN3091, Lithium metal batteries contained in equipment, *or* Lithium metal batteries packed with equipment,'' ''UN3480, Lithium ion batteries,'' and ''UN3481, Lithium ion batteries contained in equipment *or* Lithium ion batteries packed with equipment.'' This new stowage provision requires damaged or defective lithium batteries that are offered for transportation in accordance with § 173.185(f) or being transported for purposes of disposal or recycling in accordance with § 172.203(i)(4), to be stowed in accordance with stowage category C. Stowage category C requires on deck stowage instead of the currently authorized on deck or under deck stowage of these types of lithium batteries. This revision harmonizes HMR stowage requirements for lithium batteries that are damaged/defective and those that are being offered for disposal or recycling with the IMDG Code stowage requirements. This stowage change to require on deck stowage allows for more easily identifiable and effective response actions in the event of a fire involving lithium batteries onboard a vessel. PHMSA expects that these revised shipping requirements will contribute to the safe transportation of increased volumes of lithium batteries anticipated as a result of the increased use of those technologies in the transportation and other economic sectors. In response to the NPRM, PHMSA received a comment from MDTC in support of this revision.

• New stowage code 157 is assigned to the five HMR UN1950 aerosol entries and the three UN2037 receptacles; small, containing gas or gas cartridges entries. This new stowage provision requires aerosols and receptacles for gas transported for recycling or disposal to be stowed in accordance with vessel stowage category C and clear of living quarters. The HMR does not currently contain separate stowage provisions for aerosols or receptacles small containing gas that are being offered for disposal or recycling. These five UN1950 aerosol entries and the three UN2037 receptacle entries are currently assigned stowage category A. The change from stowage category A to category C means these materials being offered for recycling or disposal are required to be stowed ''on deck only'' instead of the currently authorized ''on deck or under deck.'' This revision in stowage requirements for aerosols and receptacles small

[32] 78 FR 65453 (Oct. 31, 2013). This rule affected rules HM–215K, HM–215L, HM–218G, and HM–219.

[33] International Maritime Organization Sub-Committee on the Carriage of Cargoes and Containers CCC 5/6/3.

containing gas provides more restrictive stowage requirements for these articles that have been utilized and are being offered for transportation under generally more relaxed packaging standards than if they were being offered as new articles. This more restrictive stowage requirement more easily facilitates a response effort should one be required aboard a vessel.

Third, in the paragraph (c)(2) table, PHMSA amends stowage provisions for notes 19E and 22E. When assigned to an HMT entry, these existing notes require separation ''away from'' explosives containing chlorates or perchlorates and ''away from'' ammonium compounds and explosives containing ammonium compounds or salts. PHMSA is amending these stowage provisions to specify a more demanding ''separated from'' stowage requirement. The terms ''away from'' and ''separated from'' have various meanings based on the type of shipment (*e.g.,* break-bulk, shipments within a container, or container to container). Generally speaking, the term ''separated from'' requires more stringent segregation. As an example, for segregation from one container to another if ''away from'' applies, the containers cannot be stowed one on top of the other. If ''separated from'' is assigned, the containers cannot be stowed in the same vertical line. For more information on the applicability of these terms please, *see* § 176.83 of the HMR. This revision also harmonizes the HMR with the IMDG Code and aligns with HMR stowage requirements for shipments of ammonium nitrates, chlorates, and perchlorates. These revisions provide additional segregation between loads of incompatible materials and decrease the likelihood of a reaction if a release were to occur onboard a vessel.

F. Part 178

Section 178.3

Part 178 contains specifications for packagings. Section 178.3 prescribes marking requirements for specification packagings. PHMSA amends paragraph (a)(4) to clarify the marking size requirement for packagings transporting solids with a 30 kg (66 pounds) maximum net mass. Additionally, PHMSA is amending the exception for reducing the size of the required package marking applicable to packagings with a capacity of 5 L or less, or of 5 kg maximum net mass. The existing HMR text only refers to capacity, and the use of ''maximum net mass'' is a more appropriate standard for packagings intended for solids. This editorial revision is intended to reduce confusion over the application of the reduced size marking requirements as they apply to packagings used for solid materials. The quantity limit should be based on the net amount of solid material and not the capacity of the packaging the material is placed in. This clarification is consistent with similar provisions for solids (net mass) and liquids (capacity) throughout the HMR. Ensuring the appropriate application of the reduced size marking allowance provides consistency across persons using the reduced sized marking and therefore, improves safety of transport.

Section 178.71

Section 178.71 prescribes specifications for UN pressure receptacles. To maintain consistency with the UNMR, PHMSA is updating four ISO documents incorporated by reference in this section.

First, PHMSA amends paragraph (d)(2), which outlines the configuration and design requirements for a cylinder's service equipment and includes items that prevent the release of the pressure receptacle contents during handling and transportation. Currently, this paragraph requires that valves for service equipment must conform to the 1999, 2006, and 2014 editions of ISO 10297. ISO 10297 specifies design, type testing, and marking requirements for cylinder valves fitted to refillable transportable gas cylinders, main valves for cylinder bundles, and cylinder valves or main valves with an integrated pressure regulator (VIPR), which convey compressed, liquefied, or dissolved gases. PHMSA is modifying the valve conformance requirements in this paragraph such that when the use of a valve is prescribed, the valve must conform to the requirements of ISO 10297:2014 and the supplemental amendment, ISO 10297:2014/Amd 1:2017. ISO 10297:2014/Amd 1:2017 corrects errors in ISO 10297:2014, and also includes modifications for valves used on tubes and pressure drums. PHMSA has reviewed this supplemental amendment as part of its regular participation in the review of amendments for the UNMR and does not expect any degradation of safety standards in association with the use of these two documents. Additionally, PHMSA is adding an end date of December 31, 2022, to the authorization to use ISO 10297:2014 when not used in conjunction with the supplemental 2017 amendment, ISO 10297:2014/Amd 1:2017.

Second, in this paragraph, PHMSA is amending references to ISO 14246, ''*Gas cylinders—Cylinder valves—Manufacturing tests and examinations.*'' Currently, paragraph (d)(2) states that valves must be initially inspected and tested in accordance with ISO 14246:2014(E), ''*Gas cylinders—Cylinder valves—Manufacturing tests and examinations.*'' However, in 2017, ISO published ISO 14246:2014/Amd 1:2017, ''*Gas cylinders—Cylinder valves—Manufacturing tests and examinations,*'' which provides supplemental amendments pertaining to specific pressures to be used in the pressure test and leakproofness test of acetylene valves. PHMSA mandates the use of this amended document in § 178.71 to require acetylene valve users to use the updated values in ISO 14246:2014/Amd 1:2017. PHMSA has reviewed these documents as part of its regular participation in the review of amendments for the UNMR and does not expect any degradation of safety standards in association with the use of these two documents. PHMSA is also adding analogous compliance requirements for self-closing valves to paragraph (d)(2). ISO 17879:2017—*Gas cylinders—Self-closing cylinder valves*—Specification and type testing, specifies the design, type testing, marking, and manufacturing tests and examinations requirements for self-closing cylinder valves intended to be fitted to refillable transportable gas cylinders which convey compressed, liquefied, or dissolved gases.

Third, PHMSA amends paragraph (l)(1), which specifies the design and construction requirements for UN composite cylinders and tubes. This revision adds a new subparagraph (iv) to reference ISO 11119–4:2016, ''*Gas cylinders—Refillable composite gas cylinders—Design, construction and testing—Part 4: Fully wrapped fibre reinforced composite gas cylinders up to 150 L with load-sharing welded metallic liners.*'' This document, which was adopted in the UNMR, specifies requirements for composite gas cylinders with load-sharing welded liners between 0.5 L and 150 L water capacity and a maximum test pressure of 450 bar for the storage and transportation of compressed or liquefied gases. PHMSA incorporates by reference the first three parts of the ISO 11119 series, which cover various designs of composite cylinders with a seamless liner. This fourth part defines the requirements for design, construction, and testing of composite cylinders with a welded metallic liner. Incorporating this ISO standard eliminates the need and associated burden for manufacturers to request a special permit to construct fully wrapped fiber reinforced composite gas

cylinders with load-sharing welded steel liners.[34]

Finally, PHMSA amends paragraph (o)(1) of this section to update the reference to ISO 11114–1:2012(E), ''*Gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 1: Metallic materials.*'' ISO 11114–1:2012 provides requirements for the selection of safe combinations of metallic cylinder and valve materials and cylinder gas content. PHMSA is amending the compatibility requirements to also require compatibility with the 2017 supplement to ISO 11114–1:2012, (ISO 11114–1:2012/Amd 1:2017) for material compatibility requirements. Permitting the use of this document allows shippers to safely transport a wider variety of gases in newly developed types of metallic cylinders and valves. PHMSA has reviewed this document as part of its regular participation in the review of amendments for the 21st revised edition of the UNMR and expects that adding it to the HMR will enhance the current safety of hazardous materials in transportation, in addition to harmonizing the HMR with international requirements. This amendment provides compatibility requirements for the selection of combinations of metallic cylinder and valve materials for use with gas or gas mixtures. In the interest of providing uniformity with regard to reference standards used domestically and internationally, PHMSA is revising the compatibility requirements to also refer to the 2017 amendment of this ISO standard. This 2017 supplemental amendment provides more explicit instructions on the permissible concentrations of certain gases. PHMSA has determined that permitting the use of this updated document allows safe transport of a wider variety of gases in newly developed types of metallic cylinders and valves without compromising safety.

Section 178.75

Section 178.75 prescribes specifications for multiple element gas containers (MEGCs), which are assemblies of UN cylinders, tubes, or bundles of cylinders interconnected by a manifold and assembled within a framework. The term includes all service equipment and structural equipment necessary for the transport of gases including hazardous materials marked as Division 2.1 (such as compressed hydrogen). PHMSA revises paragraph (d) to permit explicitly the use of composite construction, which is allowed for other pressure vessels (*i.e.,* cylinders), rather than limiting authorized material of construction for an MEGC to seamless steel as in the current HMR. Further, and in response to a comment from Luxfer Gas Cylinders to the NPRM, PHMSA is clarifying that composite cylinders constructed of carbon, fiberglass, or a hybrid composite can use any metallic liners or non-load sharing polymer liners and not just high strength aluminum liners. When the specifications for MEGCs were originally created, there were no standards for composite pressure receptacles in the international transport standards or the HMR. In the decades since, standards for the use of ISO composite pressure receptacles have been developed and authorized. International standards did not consider a corresponding allowance to use these composite pressure receptacles as elements of MEGCs when the specifications were originally adopted. The 21st revised edition of the UNMR has been updated to include such an authorization and PHMSA is similarly allowing the use of composite pressure receptacles in MEGCs.

To that end, PHMSA is adding references to the following ISO design standards for composite MEGCs: ISO 11119–1:2012(E), ''*Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 1: Hoop wrapped fibre reinforced composite gas cylinders and tubes up to 450 L,*'' ISO 11119–2:2012(E), ''*Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 2: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 L with load-sharing metal liners,*'' ISO 11119–3:2013(E), ''*Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 3: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 L with non-load-sharing metallic or non-metallic liners*'' and ISO 11119–4:2016, ''*Gas cylinders—Refillable composite gas cylinders—Design, construction and testing—Part 4: Fully wrapped fibre reinforced composite gas cylinders up to 150 L with load-sharing welded metallic liners,*'' The 19th revised edition of the UNMR amended the definition of a tube to include composite construction and this revision also included standards for the construction of composite tubes. Due to the lack of any technical or safety concerns, the 21st revised edition of the UNMR included an amendment to the definition of MEGCs which provides for composite construction, in addition to stainless steel construction, and was not intended to exclude MEGCs. With these revisions, PHMSA expects that this will provide flexibility and opportunities for cost savings for manufacturers of MEGCs without compromising safety. Additionally, authorizing alternative MEGC packaging construction provides flexibility in packaging selection for shippers that could facilitate the transportation of hydrogen or other gases that may be used to support clean energy alternatives.

Section 178.275

Section 178.275 outlines requirements and definitions pertaining to UN portable tanks intended for the transportation of liquid and solid hazardous materials. Paragraph (i) specifies the capacity requirements for pressure relief devices that must be used on these portable tanks. The HMR specify a formula that can be used to determine the required total capacity for these pressure relief devices. The formula defines variable ''U'' as ''thermal conductance of the insulation.'' Discussions held by the UNSCOE[35] led to the conclusion that usage of the phrase ''thermal conductance'' associated with the variable ''U'' in this formula is misleading because, in general scientific usage, ''conductance'' is expressed in ''kW. K–1'' and is not a surface factor. Leaving the formula description as it currently appears in the HMR may cause confusion for those who use it given that the correct term for the unit given is ''heat transfer coefficient.'' PHMSA is replacing the phrase ''thermal conductance'' with ''heat transfer coefficient'' so that ''U'' is defined as ''heat transfer coefficient of the insulation'' which is more appropriate for what is being calculated and is consistent with use of the formula in the UNMR. This ensures proper calculation of the total capacity for the pressure relief devices for these portable tanks.

Section 178.505

Section 178.505 prescribes specifications for aluminum drums and paragraph (b) prescribes the construction requirements for those aluminum drums. PHMSA adds a new paragraph (b)(6) to specify conditions when internal protective coatings or treatments must be applied to these

[34] See, *e.g.,* Special Permit 14457 (Dec. 16, 2019), which served as the technical basis for the development of ISO 11119–4:2016.

[35] ''Use of the terms ''conductivity'' and ''conductance'' in chapter 6.7'' *https://www.unece.org/fileadmin/DAM/trans/doc/2018/dgac10c3/ST-SG-AC.10-C.3-2018-56e.pdf.*

drums—consistent with requirements for other metal packagings, such as steel drums, as provided in § 178.504(b)(7) and aluminum and steel jerricans in § 178.511(b)(5). In response to the NPRM, RIPA provided comments in opposition to adding the new § 178.505(b)(6). RIPA believes that if adopted, this revision would require a manufacturer or reconditioner to apply ''suitable internal protective coatings or treatments'' to exposed parts of drums if needed to ensure compatibility with the lading and ensure that the applied coatings or treatments retain their protective properties under normal conditions of transport. RIPA believes that § 173.24(e) already obligates the offeror with ensuring compatibility between the packaging and the material it contains.

PHMSA finds that RIPA does not provide adequate justification for its preferred position. As noted in RIPA's comments, similar requirements in the HMR already exist for steel drums in § 178.504(a)(7) and for aluminum and steel jerricans in §§ 178.504(b)(7) and 178.511(b)(5). PHMSA is not aware of issues voiced by offerors associated with these compatibility requirements that are already a part of packaging specification requirements in the HMR. Also, RIPA did not present any specific cases of cause for concern involving steel drums or aluminum or steel jerricans that are currently subject to this requirement in the HMR. As such, PHMSA declines to adopt RIPA's comment and instead adopts the amendment to § 178.505(b)(6) as proposed.

As stated in the NPRM, PHMSA finds that since metals are susceptible to corrosion from exposure to certain chemicals (*e.g.,* sodium hydroxide solution, or alkaline liquids), measures need to be taken to ensure the packaging is compatible with the contents. Further, the general requirements for packagings in the HMR include a compatibility requirement such that even though certain packagings are specified in the HMR, it is—nevertheless—the responsibility of the person offering a hazardous material for transportation to ensure that such packagings are compatible with their contents. This applies particularly to corrosivity, permeability, softening, premature aging, and embrittlement (*see* § 173.24(e)).

As part of this final rule, PHMSA adds conditions specifying when internal protective coatings or treatments must be applied to metal drums that are not constructed of steel or aluminum. This addition is consistent with international standards covering UN 1B1 and 1B2 aluminum drums. PHMSA expects that this revision will improve consistency with regard to safety standards (*e.g.,* packaging integrity) across similar packagings. Therefore, PHMSA is revising § 178.505(b)(6) to specify conditions when internal protective coatings or treatments must be applied to aluminum drums.

Section 178.506

Section 178.506 prescribes specifications for metal drums that are not made of steel or aluminum, and paragraph (b) prescribes the construction requirements for these drums. In the NPRM, PHMSA proposed to add a new paragraph (b)(6) to specify conditions when internal protective coatings or treatments must be applied to metal drums that are not constructed of steel or aluminum consistent with this requirement for specifications of other metal packagings. This new requirement mirrors the requirements to apply suitable internal protective coatings or treatments in § 178.504(b)(7) for steel drums and § 178.511(b)(5) for aluminum and steel jerricans. In response to the NPRM, RIPA provided the same comments to § 178.505(b)(6) for aluminum drums as for this § 178.506(b)(6) for metal drums not made of steel or aluminum. PHMSA's response is the same as for the aluminum drums as discussed above in the Section 178.505 discussion.

As stated in the NPRM, PHMSA asserts that since metals are susceptible to corrosion from exposure to certain chemicals (*e.g.,* sodium hydroxide solution, or alkaline liquids), PHMSA determined measures need to be taken to ensure the packaging is compatible with the contents. Further, the general requirements for packagings in the HMR include a compatibility requirement such that even though certain packagings are specified in the HMR, it is—nevertheless—the responsibility of the person offering a hazardous material for transportation to ensure that such packagings are compatible with their contents. This applies particularly to corrosivity, permeability, softening, premature aging, and embrittlement (*see* § 173.24(e)).

However, PHMSA expects that codifying specific conditions in which internal protective coatings or treatments must be applied to metal drums that are not constructed of steel or aluminum will provide needed consistency by providing uniform safety standards for similar packagings across the HMR and ensure safe packaging and transport within these metal drums. Therefore, PHMSA revises § 178.506(b)(6) to specify conditions when internal protective coatings or treatments must be applied to metal drums that are not constructed of steel or aluminum.

Section 178.609

Section 178.609 provides test requirements for packagings for infectious substances. PHMSA makes an editorial amendment in paragraph (g) to clarify the performance testing requirements for infectious substances packaging. Specifically, PHMSA is amending paragraph (g) to clarify that only one additional test is required for packages for infectious substances containing dry ice. The 21st revised edition of the UNMR made a similar clarification regarding the testing requirements for these packagings and PHMSA has determined that the current HMR also contains conflicting language in § 178.609. Currently paragraph (g), which specifies additional testing requirement for packagings intended to contain dry ice, may be interpreted to either require five additional samples dropped once each, or one additional sample packaging dropped five times. However, requiring one sample to be dropped five times in one orientation would not be consistent with drop testing requirements applicable to other packagings. PHMSA amends paragraph (g) to clearly state only one additional sample must be dropped in a single orientation; namely, the orientation the tester determines would be most likely to result in failure of the packaging in light of the properties of the packaging and the test surface. PHMSA does not consider this revision to be technical, but editorial, with the intent of conveying the testing protocol, as it was designed, more clearly. For that reason, PHMSA does not expect any change in level of safety than what was originally intended. This revision simply results in a package being tested in line with the design of the original packaging test method.

Section 178.703

Section 178.703 describes the marking requirements for IBCs. In the NPRM, PHMSA proposed to amend two marking requirements in this section.

In paragraph (b)(6), which specifies additional marking requirements for composite IBCs, PHMSA proposed an amendment to specify that the required markings on inner receptacles of these packagings must either be readily visible while in the outer packaging or duplicated on the outer packaging to facilitate inspection verifying compliance with the applicable package

performance standard marking requirements.

RIPA provided comments supportive of harmonizing § 178.703 of the HMR with the newly adopted UNMR provision to require inner receptacle markings of an IBC that are not visible to be duplicated on the outer packaging of the IBC. However, RIPA notes that the proposed language contains an additional requirement that the duplicated inner receptacle mark appearing on the IBC body be identified as duplicating the inner receptacle marking. RIPA adds that PHMSA does not indicate the form this identification should take, which could lead to regulatory disharmony and enforcement confusion because these marks will likely differ from one another if left to the discretion of each IBC manufacturer and preprocessor. RIPA suggests that the proposed requirement ensure the duplicated inner mark is placed ''near'' the primary and additional marking and the mark itself to indicate it is a duplicate of the inner receptacle mark. RIBCA submitted a comment agreeing with the proposed amendment.

In response to the comments from RIPA and RIBCA, PHMSA clarifies that copying of the inner receptacle marking on the outer packaging must be consistent. PHMSA confirms it is permissible to include the ''/B'' mark to indicate that the inner receptacle mark is a duplicate marking. However, PHMSA does not agree it is necessary to require this additional information by way of regulatory text—PHMSA submits the guidance in this preamble discussion should suffice to elaborate on PHMSA's intent in revising § 178.703. For clarification, it is expected that the marking replicated on the outer packaging of the IBC should be the same as the marking on the inner receptacle and placed in a visible location in the vicinity of the outer receptacle marking.

Therefore, PHMSA is revising § 178.703(b)(6) to require that markings on inner receptacles of composite IBCs must either be readily visible while in the outer packaging or duplicated on the outer packaging to facilitate inspection verifying compliance with the applicable package performance standard marking requirements.

In paragraph (b)(7), which outlines the marking requirements for IBCs that are designed to be stacked, PHMSA proposed to revise the language in paragraph (b)(7)(iv) to clarify the maximum stacking load requirements pertaining to each marking requirement. Currently paragraph (b)(7)(iv) indicates that the maximum permitted stacking load ''applicable when the IBC is in use,'' must be displayed. In the NPRM, PHMSA made the case that this phrase may be misinterpreted to mean that the stacking load applies only to transportation, leading to these packagings being stacked inappropriately when not in transportation, such as in warehouse storage.

PHMSA received comments from RIBCA and RIPA on the IBC stacking mark. RIBCA generally agrees with the proposed revision but believes the words ''applicable when the IBC is in use'' is too ambiguous. RIBCA adds that the required marking for the stacking load limit specified in the UNMR is based on anticipated dynamic forces that may be encountered in transport and such potential forces are not present in other settings such as storage. RIPA also notes that higher stacking loads have not proven to pose a concern in storage where IBCs may safely be stacked with loads exceeding the marked limit. Additionally, RIPA suggests that PHMSA clarify this provision while remaining within the bounds of its regulatory authority by retaining the existing phrasing and simply replacing the word ''use'' with ''transportation,'' which includes storage incidental to movement.

PHMSA agrees with comments by RIBCA and RIPA that as proposed, the revision to (b)(7)(iv) goes beyond the statutory authority for regulations of hazardous materials in transportation and the intended regulation applying to the safety of stacking IBCs when transported in commerce. Therefore, PHMSA is adjusting the proposed amendment to § 178.703(b)(6) to revise the phrase ''applicable when the IBC is in use'' to instead read ''applicable when the IBC is in transportation'' to clarify that stacking loads should never be exceeded when in transportation including when stored incidental to movement. Clarifying the regulatory text regarding the proper handling of these packagings will provide an enhanced level of safety both during transport and during storage incidental to that transportation. This revision addresses RIPA and RIBCA's concern that the stacking mark revision will affect IBCs while stacked in storage.

Section 178.705

Section 178.705 prescribes specifications for metal IBCs. Paragraph (c) outlines construction requirements and paragraph (c)(1)(iv) specifies the minimum wall thickness requirements for metal IBCs. Metal IBCs are currently the only type of IBCs for which there are minimum wall thickness requirements, which is likely a holdover from regulations for cubical tank containers, from which the metal IBCs were once derived.[36] In contrast, because of performance testing requirements' (*i.e.,* drop, stack, and vibration) ability to demonstrate the integrity of the package, the 21st revised edition of the UNMR include an amendment which now provides that minimum wall thickness requirements apply only to metal IBCs that have a capacity of more than 1500 L (396 gallons), while metal IBCs with a volume of 1500 L or less are no longer subject to previous prescriptive minimum wall thickness requirements.

In the NPRM, PHMSA proposed to revise the minimum wall thickness requirements for metal IBCs with a volume of 1500 L or less to provide additional design and construction flexibility. This revision harmonizes the minimum wall thickness requirements for IBCs with the 21st revised edition of the UNMR. In response to this proposal, PHMSA received comments from Dow, DGAC, and RIBCA in support of revising the minimum wall thickness requirements in § 178.705.

Additionally, Dow, DGAC, and RIBCA all state their opposition to the alternative outlined in the NPRM for metal IBC wall thickness in § 171.23. The alternative for § 171.23 would have prescribed requirements for specific materials and packagings transported under incorporated international standards and prohibited transportation or offering for transportation of metal IBCs with a capacity of 1500 L or less. The alternative would have applied when that transportation is made in accordance with the ICAO Technical Instructions, IMDG Code, Transport Canada TDG Regulations, or the IAEA Regulations. However, due to the fact that PHMSA did not receive any additional information in response to the questions presented in the NPRM, the alternative—as outlined in § 171.23 of the NPRM—is not being pursued at this time.

Therefore, PHMSA is revising the minimum wall thickness requirements in § 178.705 for metal IBCs with a volume of 1500 L or less. These revisions will provide additional design and construction flexibility. Additionally, this amendment will harmonize the HMR with the 21st revised edition of the UNMR.

Lastly, in response to the NPRM, RIPA notes that there are dozens of

[36] Stainless Steel Container Association, Proposal on Minimum Wall Thickness for Metal IBCs Submitted to the Sub-Committee of Experts on the Transport of Dangerous Goods During the 54th Session (Sep. 7, 2018), *https://www.unece.org/fileadmin/DAM/trans/doc/2018/dgac10c3/ST-SG-AC.10-C.3-2018-96e.pdf.*

metal IBC styles in use today with capacities ranging from approximately 416 L (110 gallons) up to 1500 L (496 gallons) that are manufactured using several kinds of steels, including carbon steel and several varieties of stainless steel designed to carry highly corrosive and toxic materials. RIPA believes it would be beneficial if PHMSA took the time to assess the types and quantities of materials shipped in metal IBCs before determining if the existing metal thickness requirement should be dropped for these packagings.

PHMSA appreciates RIPAs comments and will take these comments into consideration for further action in the future. Additionally, PHMSA encourages RIPA to submit a petition for rulemaking in accordance with § 106.100 providing data and arguments for why PHMSA should or should not expand the minimum wall thickness criteria to other types and quantities of materials shipped in IBCs.

G. Part 180

Section 180.207

Section 180.207 outlines the requirements for the requalification of UN pressure receptacles. Paragraph (d) specifies the requalification procedures for various types of UN cylinders but, consistent with historical approach of the UNMR, does not include any procedures for the periodic inspection of UN cylinder bundles. However, the 21st revised edition of the UNMR addressed that gap by adding a new reference document entitled ISO 20475: 2018 ''*Gas cylinders—Cylinder bundles—Periodic inspection and testing.*'' ISO 20475 provides detailed procedures for maintenance and periodic inspection of cylinder bundles.

PHMSA adds paragraph (d)(7) to reference ISO 20475:2018, ''*Gas cylinders—Cylinder bundles—Periodic inspection and testing*'' providing a requalification standard for UN cylinder bundles because requalification procedures may differ for bundles of cylinders versus individual cylinders. This document was developed based on the need for a standard specific to cylinder bundles which would allow these cylinders to be reintroduced into service for an extended period of time. PHMSA expects that incorporating by reference a safety standard for requalification will reduce business costs and environmental effects by allowing existing cylinders to be reintroduced into service for continued use. As a participant on the UNSCOE, this standard was reviewed by PHMSA and other international bodies for inclusion in the UNMR based on its need and safety merit. Incorporating by reference ISO 20475 in the HMR is necessary, not only for international harmonization, but also to address the lack of such a standard in the HMR.

Additionally, PHMSA is removing a reference to the outdated, third edition of ISO 10462(E), ''*Gas cylinders—Transportable cylinders for dissolved acetylene—Periodic inspection and maintenance*'' in paragraph (d)(3) used for the requalification of dissolved acetylene cylinders. Requalification is required in accordance with the third edition of ISO 10462:2013(E); however, requalification in accordance with the second edition was authorized until December 31, 2018, in § 180.207(d)(3). This date has since passed and, therefore, PHMSA is removing the reference from this section of the HMR. Consistent with this revision, the incorporation by reference of the second edition is removed from § 171.7(w) of the HMR. Additionally, acetylene cylinders requalified in accordance with the second edition before December 31, 2018, must be subsequently requalified in accordance with referenced third edition. PHMSA expects that these amendments will enhance safety by providing cylinder users with the necessary guidelines for the continued use of UN cylinders.

The regulatory text references ISO 10462:2013(E), which was previously approved for incorporation by reference in this section, and no changes are being made to this standard.

VI. Regulatory Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This final rule is published under the authority of Federal hazardous materials transportation law (49 U.S.C. 5101 *et seq.*), which authorizes the Secretary of Transportation to prescribe regulations for the safe transportation of hazardous materials—including security—in intrastate, interstate, and foreign commerce. Additionally, 49 U.S.C. 5120 authorizes the Secretary to consult with interested international authorities to ensure that, to the extent practicable, regulations governing the transportation of hazardous materials in commerce are consistent with the standards adopted by international authorities. The Secretary has delegated the authority granted in the Federal hazardous materials transportation law to the PHMSA Administrator at 49 CFR 1.97(b).

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866 (''Regulatory Planning and Review'') [37] requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' Similarly, DOT Order 2100.6A (''Policies and Procedures for Rulemakings'') [38] requires that PHMSA rulemaking actions include ''an assessment of the potential benefits, costs, and other important impacts of the regulatory action,'' and any significant distributional impacts, including any environmental impacts.

Executive Order 12866 and DOT Order 2100.6A require that PHMSA submit ''significant regulatory actions'' to OMB for review. This rulemaking is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was not formally reviewed by OMB. This rulemaking is also not considered a significant rule under DOT Order 2100.6A.

The following is a brief summary of costs, savings, and net benefits of some of the amendments in this final rule. In the RIA, PHMSA developed a more detailed analysis of these costs and benefits, and a copy of it has been placed in the rulemaking docket.

PHMSA is amending the HMR to maintain alignment with international regulations and standards, thereby maintaining the high safety standard currently achieved under the HMR, facilitating the safe transportation of critical vaccines and other medical materials associated with the response to the COVID–19 public health emergency, and aligning HMR requirements with anticipated increases in the volume of lithium batteries transported in interstate commerce from electrification of the transportation and other economic sectors. PHMSA examined the likely impacts of finalizing and implementing the provisions in the final rule in order to assess the benefits and costs of these amendments. This analysis allowed PHMSA to quantitatively assess the material effects of three of the amendments in this final rule. The effects of six remaining amendments are not quantified but are assessed qualitatively.

[37] 58 FR 51735 (Oct. 4, 1993).

[38] *https://www.transportation.gov/sites/dot.gov/files/2021-06/DOT-2100.6A-Rulemaking-and-Guidance-%28003%29.pdf.*

PHMSA estimates that the annualized quantified net cost savings of this rulemaking, using a seven percent (7%) discount rate, are approximately $24.5 to $28.3 million per year. The table below presents a summary of the monetized impacts of changes made in this final rule. PHMSA notes that its estimated net cost savings below are consistent with the estimates within the Preliminary Regulatory Impact Assessment (PRIA) supporting the NPRM:

SUMMARY TABLE OF NET REGULATORY COST SAVINGS, DISCOUNT RATE = 7%, 2022–2031
[$2019]

Rule amendments	10 Year costs		10 Year cost savings		10 Year net cost savings		Annual costs		Annual cost savings		Annual net cost savings	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Amendment 2: Electric and Electronic Detonators	$637,197	$862,238	0	0	($637,197)	($862,238)	$90,723	$122,763	0	0	($90,723)	($122,763)
Amendment 5: Lithium Battery Mark	0	0	$166,458,847	$171,243,943	166,458,847	171,243,943	0	0	$23,699,995	$24,381,285	23,699,995	24,381,285
Amendment 7: Data Loggers	0	0	6,443,740	28,443,710	6,443,740	28,443,710	0	0	917,444	4,094,744	917,444	4,094,744
Total	637,197	862,238	172,902,587	199,687,653	172,265,389	198,825,414	90,723	122,763	24,617,438	28,431,029	24,526,716	28,308,266

Although PHMSA received comments on its anticipated safety benefits in the rulemaking (discussed above in Section IV), PHMSA received one comment that hints at an overstatement of the benefits of the rule when considering the quantification of compliance costs, including increased training costs for compliance. However, the comment provided no quantifiable data to rebut the compliance costs PHMSA proposed in the PRIA. No additional comments were received from stakeholders on PHMSA's quantification of compliance costs and benefits within the PRIA. The safety and environmental benefits of the final rule have not been quantified. However, PHMSA expects these amendments will help to improve public safety and reduce the risk of environmental harm by maintaining consistency between these international regulations and the HMR. Harmonization of the HMR with international consensus standards may reduce delays and interruptions of hazardous materials during transportation, thereby lowering GHG emissions and safety risks to communities—including minority, low-income, underserved, and other disadvantaged populations and communities—in the vicinity of interim storage sites and transportation arteries and hubs.

C. Executive Order 13132

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism'')[39] and the Presidential memorandum (''Preemption'') that was published in the **Federal Register** on May 22, 2009.[40] Executive Order 13132 requires agencies to assure meaningful and timely input by state and local officials in the development of regulatory policies that may 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.''

The rulemaking may preempt state and local, and Native American Tribe requirements, but does not revise any regulation that has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. The federal hazardous materials transportation law contains an express preemption provision at 49 U.S.C.5125(b) that preempts state, local, and tribal requirements on certain covered subjects, unless the non-federal requirements are ''substantively the same'' as the federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses covered subject items (1), (2), (3), (4), and (5) above and preempts State, local, and Tribal requirements not meeting the ''substantively the same'' standard. In this instance, the preemptive effect of the final rule is limited to the minimum level necessary to achieve the objectives of the hazardous materials transportation law under which the final rule is promulgated. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13175

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments'')[41] and DOT Order 5301.1 (''Department of Transportation Policies, Programs, and Procedures Affecting American Indians, Alaska Natives, and Tribes''). Executive Order 13175 and DOT Order 5301.1 require DOT Operating Administrations to assure meaningful and timely input from Native American Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship and distribution of power between the federal government and Native American Tribes.

PHMSA assessed the impact of the rulemaking and determined that it does not significantly or uniquely affect Tribal communities or Native American Tribal governments. The changes to the HMR as written in this final rule are facially neutral and have broad, national scope; PHMSA, therefore, expects this rulemaking not to significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Native American

[39] 64 FR 43255 (Aug. 10, 1999).

[40] 74 FR 24693 (May 22, 2009).

[41] 65 FR 67241 (Nov. 9, 2000).

Tribal governments or mandate Tribal action. Because PHMSA expects the rulemaking will not adversely affect the safe transportation of hazardous materials generally, PHMSA does not expect it will entail disproportionately high adverse risks for Tribal communities. For these reasons, PHMSA finds the funding and consultation requirements of Executive Order 13175 and DOT Order 5301.1 do not apply.

E. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to review regulations to assess their impact on small entities, unless the agency head certifies that a rulemaking will not have a significant economic impact on a substantial number of small entities including small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where possible to do so and still meet the objectives of applicable regulatory statutes. Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'')[42] requires agencies to establish procedures and policies to promote compliance with the Regulatory Flexibility Act and to ''thoroughly review draft rules to assess and take appropriate account of the potential impact'' of the rules on small businesses, governmental jurisdictions, and small organizations. The DOT posts its implementing guidance on a dedicated web page.[43]

This final rule has been developed in accordance with Executive Order 13272 and with DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of draft rules on small entities are properly considered. This final rule facilitates the transportation of hazardous materials in international commerce by providing consistency with international standards. It applies to offerors and carriers of hazardous materials, some of whom are small entities, such as chemical manufacturers, users, and suppliers, packaging manufacturers, distributors, and training companies. As discussed at length in the RIA in the rulemaking docket, the amendments in this rule should result in net cost savings that will ease the regulatory compliance burden for those and other entities engaged in domestic and international commerce, including trans-border shipments within North America. Additionally, the changes in this final rule will relieve U.S. companies—including small entities competing in foreign markets—from the burden of complying with a dual system of regulations. Therefore, PHMSA certifies that these amendments will not, if adopted, have a significant economic impact on a substantial number of small entities.

F. Paperwork Reduction Act

PHMSA has analyzed this final rule in accordance with the Paperwork Reduction Act. PHMSA currently accounts for shipping paper burdens under OMB Control Number 2137–0034, ''Hazardous Materials Shipping Papers and Emergency Response Information.'' PHMSA makes a number of amendments that may impact the burden accounted for in OMB Control Number 2137–0034. They include requiring the word ''stabilized'' as a part of the proper shipping name for ''UN2522, 2-Dimethlaminoethl methacrylate,'' adding the applicable term ''DAMAGED/DEFECTIVE,'' ''LITHIUM BATTERIES FOR DISPOSAL'' or ''LITHIUM BATTERIES FOR RECYCLING,'' excepting marine pollutants from the requirement to supplement the proper shipping name with a technical name for UN3077 and UN3082 and requiring documentation of the holding time for refrigerated liquefied gases transported in portable tanks. However, while PHMSA estimates that there will be some impact in the annual burden related to shipping papers, PHMSA expects the overall impact to annual burden is negligible in relation to the number of burden hours currently associated with this information collection.

OMB Control Number 2137–0051, ''Rulemaking, Special Permits, and Preemption Requirements,'' currently accounts for burden associated with petitions for rulemaking, special permit applications, and preemption requests. PHMSA is authorizing certain ISO standard valves in § 173.301b(c)(2) and expands § 175.10 to allow passenger and crewmembers to carry certain Division 2.2 aerosols in carry-on baggage, both of which eliminate the need for use of a special permit. While PHMSA expects these revisions to reduce the burden associated with this information collection, PHMSA anticipates the reduction is negligible in relation to the total burden hours associated with special permit applications.

PHMSA accounts for the burden from approval applications in OMB Control Number 2137–0557, ''Approvals for Hazardous Materials.'' PHMSA is adding a new HMT entry for ''UN3549, Medical Waste, Category A, Affecting Humans, *solid or* Medical Waste, Category A, Affecting Animals *only, solid*'' and require an approval for transportation in accordance with Special Provision 131, which PHMSA expects will increase the number of annual approval applicants. PHMSA also is adding new entries to the § 173.225 Organic Peroxide Table, which PHMSA expects will decrease the number of annual approval applicants. Overall, PHMSA expects that these changes are negligible to the overall impact of the total burden in relation to the number of burden hours associated with this information collection.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any NPRM or final rule that includes a federal mandate that may result in the expenditure by State, local, and Tribal governments, or by the private sector of $100 million or more in 1996 dollars in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

As explained in the RIA, this rulemaking does not impose unfunded mandates under the UMRA. It does not result in costs of $100 million or more in 1996 dollars to either State, local, or Tribal governments, or to the private sector, in any one year. A copy of the RIA is available for review in the rulemaking docket.

H. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*), requires that Federal agencies analyze actions to determine whether the action will have a significant impact on the human environment. The Council on Environmental Quality implementing regulations—*i.e.,* 40 CFR parts 1500–1508—require Federal agencies to conduct an environmental review considering: (1) the need for the action; (2) alternatives to the action; (3) probable environmental impacts of the action and alternatives; and (4) the

[42] 67 FR 53461 (Aug. 16, 2002).

[43] DOT, ''Rulemaking Requirements Related to Small Entities,'' *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities* (last accessed June 17, 2021).

agencies and persons consulted during the consideration process. DOT Order 5610.1C (''Procedures for Considering Environmental Impacts'') establishes departmental procedures for evaluation of environmental impacts under NEPA and its implementing regulations.

1. Purpose and Need

This final rule amends the HMR to maintain alignment with international consensus standards by incorporating into the HMR various amendments, including changes to proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, air transport quantity limitations, and vessel stowage requirements. PHMSA notes that the amendments in this final rule are expected to result in cost savings and reduced regulatory burden for shippers engaged in domestic and international commerce, including trans-border shipments within North America. Absent adoption of the amendments in the final rule, U.S. companies—including numerous small entities competing in foreign markets—may be at an economic disadvantage because of their need to comply with a dual system of regulations. Further, the HMR amendments introduced in this rulemaking align HMR requirements with anticipated increases in the volume of lithium batteries transported in interstate commerce from electrification of the transportation and other economic sectors that are expected to reduce the emission of greenhouse gases from the transportation sector.

As previously explained in the preamble of this final rule and the RIA (each of which are incorporated by reference in this discussion of the environmental impacts of the Selected Action Alternative), PHMSA expects the adoption of the regulatory amendments in this final rule to maintain the high safety standard currently achieved under the HMR. PHMSA has evaluated the safety of each of the amendments in this final rule individually, as well as the aggregate impact on transportation safety from adoption of this final rule. PHMSA received no comments on the draft environmental assessment within the NPRM's discussion of NEPA.

2. Alternatives Considered

In this rulemaking, PHMSA considered the following alternatives:

Alternative #1: No Action

If PHMSA were to select the No Action Alternative, current regulations remain in place and no provisions will be amended or added.

Alternative #2: Amend the HMR as Provided in This Final Rule

The final Rule Alternative would adopt the HMR amendments set forth in this final rule, and was previously referred to as the ''Proposed Action Alternative'' in the draft environmental assessment (DEA) that was included within the NPRM. The amendments included in this alternative are more fully discussed in the preamble and regulatory text sections of this final rule.

3. Reasonably Foreseeable Environmental Impacts of the Alternatives

Alternative #1: No Action

After careful consideration of public comments on the NPRM (none of which directly addressed the draft environmental assessment), and revised analyses of economic and environmental impacts of the Proposed Action Alternative, PHMSA has adopted the Proposed Action Alternative (*i.e.,* the final rule) as the Selected Action. If PHMSA selected the No Action Alternative, the HMR would remain unchanged, and no provisions would be amended or added. However, any economic benefits gained through harmonization of the HMR with updated international consensus standards—including, but not limited to, the 21st revised edition of the UNMR, the 2021–2022 ICAO Technical Instructions and Amendment 40–20 of the IMDG Code—governing shipping of hazardous materials would not be realized.

Additionally, the No Action Alternative would not adopt enhanced and clarified regulatory requirements expected to maintain the high level of safety in the transportation of hazardous materials as provided by the HMR. As explained in the preamble to the NPRM and the final rule, consistency between the HMR and current international standards can enhance safety by (1) ensuring that the HMR is informed by the latest best practices and lessons learned; (2) improving understanding of and compliance with pertinent requirements; (3) enabling consistent emergency response procedures in the event of a hazardous materials incident; and (4) facilitating the smooth flow of hazardous materials from their points of origin to their points of destination. Avoiding delays, interruptions, or reshipments associated with inconsistencies between the HMR and international standards prevents environmental impacts from: (1) increased risk of release of hazardous materials during extra tips or pauses in transportation and (2) additional fuel combustion and degradation of transportation infrastructure. PHMSA would not capture those benefits if it did not incorporate the updated international standards into the HMR under the No Action Alternative.

Additionally, some of the HMR amendments are expected to better accommodate the safe transportation of emerging technologies—in particular lithium battery technologies and adding shipping paper requirements intended to reduce the likelihood of venting refrigerated gases, including extremely potent greenhouse gases such as nitrous oxide. As explained in the RIA, PHMSA expects a significant increase in the volume of shipments of lithium batteries over time as more sectors of the U.S. domestic and international economies electrify. PHMSA's HMR amendments pertaining to lithium batteries—which touch on multiple stages in the lifecycle of a lithium battery—are intended to ensure that expansion occurs safely. The No Action Alternative, in contrast, would not amend the HMR to account for these emerging trends in the transportation of hazardous materials.

PHMSA notes that the No Action Alternative would avoid any risks to public safety and the environment from the proposed authorization of shipments of hazardous materials offered pursuant to temporary certificates issued by Transport Canada. While the transportation of hazardous materials always entails some risk, allowing the transportation of hazardous materials pursuant to temporary certificates issued by Transport Canada could facilitate shipments of hazardous materials that are not otherwise compliant with the HMR and do not meet an equivalent standard of safety. Arguably, this allowance could entail greater risks to public safety and the environment. However, based on years of collaboration, PHMSA considers Transport Canada to be a partner in hazardous materials safety and has confidence in the technical expertise and judgement of the hazardous materials safety SMEs at Transport Canada. PHMSA further submits that any risks are mitigated by (1) the technical review by Transport Canada subject matter experts to determine any shipments would be in the public interest, (2) the limited duration of those temporary certificates, (3) the terms and conditions imposed in those certificates, (4) other regulatory requirements under the TDG Regulations or the HMR that may remain applicable, and (5) PHMSA's limitation of its recognition of temporary certificates to transportation via motor carrier and rail during the

particular shipment authorized by a temporary certificate.

PHMSA expects that the No Action Alternative could have a modest negative impact on GHG emissions. PHMSA expects the differences between the HMR and international standards for transportation of hazardous materials could result in transportation delays or interruptions and anticipates that there could be modestly higher GHG emissions from some combination of (1) transfer of delayed hazardous materials to and from interim storage, (2) return of improperly shipped materials to their point of origin, and (3) re-shipment of returned materials. Also, this final rule creates requirements for the shipment of refrigerated gases, including highly potent greenhouse gases, to inform shippers and carriers about when the gases will begin venting, which could facilitate planning to prevent these environmentally harmful releases. PHMSA notes that it is unable to quantify such GHG emissions because of the difficulty in identifying the precise quantity or characteristics of such interim storage or returns/re-shipments.

Final Rule Alternative

As described above, PHMSA expects the Selected Action will yield superior benefits (cost benefits for shippers and carriers; public safety and environmental benefits; equity benefits) compared to the No Action Alternative.

4. Agencies Consulted

PHMSA expects this final rule would affect hazardous materials shippers and carriers by highway, rail, vessel, and aircraft, as well as package manufacturers and testers. PHMSA has coordinated with the Federal Aviation Administration, the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, and the United States Coast Guard in the development of this final rule. As such, PHMSA did not receive any adverse comments on the amendments in this final rule from these or any other Federal Agencies.

5. Conclusion

PHMSA has determined the adoption of the Final Rule Alternative's regulatory amendments within this final rule will maintain the HMR's current high level of safety for shipments of hazardous materials transported by highway, rail, air, and vessel, and as such finds the HMR amendments adopted in the final rule will have no significant impact on the human environment.

I. Executive Order 12898

DOT Order 5610.2C (Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'') and Executive Orders 12898 (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations''),[44] 13985 (''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government''),[45] 13990 (''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis''),[46] and 14008 (''Tackling the Climate Crisis at Home and Abroad'')[47] require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects of their programs, policies, and activities on minority populations, low-income populations, and other underserved and disadvantaged communities.

PHMSA has evaluated this final rule under the above Executive Orders and DOT Order 5610.2C. PHMSA does not expect the final rule to cause disproportionately high and adverse human health and environmental effects on minority, low-income, underserved, and other disadvantaged populations, and communities. The rulemaking is facially neutral and national in scope; it is neither directed toward a particular population, region, or community, nor is it expected to adversely impact any particular population, region, or community. And because PHMSA expects the rulemaking would not adversely affect the safe transportation of hazardous materials generally, PHMSA does not expect the revisions to involve disproportionately high adverse risks for minority populations, low-income populations, or other underserved and other disadvantaged communities.

PHMSA submits that the rulemaking could in fact reduce risks to minority populations, low-income populations, or other underserved and other disadvantaged communities. Because the HMR amendments may avoid the release of hazardous materials and reduce the frequency of delays and returned/resubmitted shipments of hazardous materials resulting from conflict between the current HMR and updated international standards, the final rule could reduce risks to populations and communities—including any minority, low-income, underserved and other disadvantaged populations and communities—in the vicinity of interim storage sites and transportation arteries and hubs. Additionally, as explained in the above discussion of NEPA, PHMSA expects that its HMR amendments will yield modest GHG emissions reductions, thereby reducing the risks posed by anthropogenic climate change to minority, low-income, underserved, and other disadvantaged populations, and communities.

J. 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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS). DOT's complete Privacy Act Statement is in the **Federal Register** published on April 11, 2000,[48] or on DOT's website at *http://www.dot.gov/privacy.*

K. Executive Order 13609 and International Trade Analysis

Executive Order 13609 (''Promoting International Regulatory Cooperation'')[49] requires that agencies consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465) (as amended, the Trade Agreements Act), prohibits agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to the Trade Agreements Act, the establishment of

[44] 59 FR 7629 (Feb. 11, 1994).
[45] 86 FR 7009 (Jan. 20, 2021).
[46] 86 FR 7037 (Jan. 20, 2021).
[47] 86 FR 7619 (Feb. 1, 2021).
[48] 65 FR 19477 (Apr. 11, 2000).
[49] 77 FR 26413 (May 4, 2012).

standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in the establishment of international standards to protect the safety of the American public, and it has assessed the effects of the final rule to ensure that it does not cause unnecessary obstacles to foreign trade. In fact, the final rule is expected to facilitate international trade by harmonizing U.S. and international requirements for the transportation of hazardous materials so as to reduce regulatory burdens and minimize delays arising from having to comply with divergent regulatory requirements. Accordingly, this rulemaking is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreements Act.

L. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs Federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specification of materials, test methods, or performance requirements) that are developed or adopted by voluntary consensus standard bodies. This rulemaking involves multiple voluntary consensus standards which are discussed at length in the discussion on § 171.7. *See* SECTION 171.7 of the ''V. Section-by-Section Review of Amendments'' for further details.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Incorporation by reference, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 175

Air carriers, Hazardous materials transportation, Radioactive materials, Reporting and recordkeeping requirements.

49 CFR Part 176

Maritime carriers, Hazardous materials transportation, Incorporation by reference, Radioactive materials, Reporting and recordkeeping requirements.

49 CFR Part 178

Hazardous materials transportation, Incorporation by reference, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 180

Hazardous materials transportation, Motor carriers, Motor vehicle safety, Packaging and containers, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 4 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 2. In § 171.7:

■ a. Revise paragraphs (a), (s)(1), (t)(1), (v)(2), and (w)(38) through (77);

■ b. Add paragraphs (w)(78) through (81); and

■ c. Revise paragraphs (aa) introductory text, (aa)(3), and (dd)(1) through (4).

The revisions and additions read as follows:

§ 171.7 Reference material.

(a) Certain material is incorporated by reference into subchapters A, B, and C with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, PHMSA must publish a document in the **Federal Register** and the material must be available to the public. All approved incorporation by reference (IBR) material is available for inspection at PHMSA and at the National Archives and Records Administration (NARA). Contact PHMSA at: The Office of Hazardous Materials Safety, Office of Hazardous Materials Standards, East Building, PHH–10, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. For information on the availability of this material at PHH–10, call 1–800–467–4922, or go to: *www.phmsa.dot.gov.* For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* The material may be obtained from the source(s) in the following paragraph(s) of this section.

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(1) IAEA Safety Standards for Protecting People and the Environment; Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements No. SSR–6 (Rev.1), (IAEA Regulations), 2018 Edition, copyright 2018; into §§ 171.22; 171.23; 171.26; 173.415 through 173.417; 173.435; 173.473.

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(t) * * *

(1) ICAO Doc 9284. Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), 2021–2022 Edition, copyright 2020; into §§ 171.8; 171.22 through 171.24; 172.101; 172.202; 172.401; 172.407; 172.512; 172.519; 172.602; 173.56; 173.320; 175.10, 175.33; 178.3.

* * * * *

(v) * * *

(2) International Maritime Dangerous Goods Code (IMDG Code), Incorporating Amendment 40–20 (English Edition), (Volumes 1 and 2), 2020 Edition, copyright 2020; into §§ 171.22; 171.23; 171.25; 172.101; 172.202; 172.203; 172.401; 172.407; 172.502; 172.519; 172.602; 173.21; 173.56; 176.2; 176.5; 176.11; 176.27; 176.30; 176.83; 176.84; 176.140; 176.720; 176.906; 178.3; 178.274.

(w) * * *

(38) ISO 10156:2017(E), Gas cylinders—Gases and gas mixtures—Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets, Fourth edition, 2017–07; into § 173.115.

(39) ISO 10297:1999(E), Gas cylinders—Refillable gas cylinder valves—Specification and type testing, First Edition, 1995–05–01; into §§ 173.301b; 178.71.

(40) ISO 10297:2006(E), Transportable gas cylinders—Cylinder valves—Specification and type testing, Second Edition, 2006–01–15; into §§ 173.301b; 178.71.

(41) ISO 10297:2014(E), Gas cylinders—Cylinder valves—Specification and type testing, Third Edition, 2014–07–15; into §§ 173.301b; 178.71.

(42) ISO 10297:2014/Amd 1:2017(E), Gas cylinders—Cylinder valves—Specification and type testing—Amendment 1: Pressure drums and tubes, Third Edition, 2017–03; into §§ 173.301b; 178.71.

(43) ISO 10461:2005(E), Gas cylinders—Seamless aluminum-alloy gas cylinders—Periodic inspection and testing, Second Edition, 2005–02–15 and Amendment 1, 2006–07–15; into § 180.207.

(44) ISO 10462:2013(E), Gas cylinders—Acetylene cylinders—Periodic inspection and maintenance, Third edition, 2013–12–15; into § 180.207.

(45) ISO 10692–2:2001(E), Gas cylinders—Gas cylinder valve connections for use in the micro-electronics industry—Part 2: Specification and type testing for valve to cylinder connections, First Edition, 2001–08–01; into §§ 173.40; 173.302c.

(46) ISO 11114–1:2012(E), Gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 1: Metallic materials, Second edition, 2012–03–15; into §§ 172.102; 173.301b; 178.71.

(47) ISO 11114–1:2012/Amd 1:2017(E), Gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 1: Metallic materials—Amendment 1, Second Edition, 2017–01; into §§ 172.102, 173.301b, 178.71.

(48) ISO 11114–2:2013(E), Gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 2: Non-metallic materials, Second edition, 2013–04; into §§ 173.301b; 178.71.

(49) ISO 11117:1998(E): Gas cylinders—Valve protection caps and valve guards for industrial and medical gas cylinders—Design, construction and tests, First edition, 1998–08–01; into § 173.301b.

(50) ISO 11117:2008(E): Gas cylinders—Valve protection caps and valve guards—Design, construction and tests, Second edition, 2008–09–01; into § 173.301b.

(51) ISO 11117:2008/Cor.1:2009(E): Gas cylinders—Valve protection caps and valve guards—Design, construction and tests, Technical Corrigendum 1, 2009–05–01; into § 173.301b.

(52) ISO 11118(E), Gas cylinders—Non-refillable metallic gas cylinders—Specification and test methods, First edition, October 1999; into § 178.71.

(53) ISO 11118:2015(E), Gas cylinders—Non-refillable metallic gas cylinders—Specification and test methods, Second edition, 2015–09–15; into §§ 173.301b; 178.71.

(54) ISO 11119–1(E), Gas cylinders—Gas cylinders of composite construction—Specification and test methods—Part 1: Hoop-wrapped composite gas cylinders, First edition, May 2002; into § 178.71.

(55) ISO 11119–1:2012(E), Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 1: Hoop wrapped fibre reinforced composite gas cylinders and tubes up to 450 l, Second edition, 2012–08–01; into §§ 178.71; 178.75.

(56) ISO 11119–2(E), Gas cylinders—Gas cylinders of composite construction—Specification and test methods—Part 2: Fully wrapped fibre reinforced composite gas cylinders with load-sharing metal liners, First edition, May 2002; into § 178.71.

(57) ISO 11119–2:2012(E), Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 2: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 l with load-sharing metal liners, Second edition, 2012–07–15; into §§ 178.71; 178.75.

(58) ISO 11119–2:2012/Amd.1:2014(E), Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 2: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 l with load-sharing metal liners, Amendment 1, 2014–08–15; into §§ 178.71; 178.75.

(59) ISO 11119–3(E), Gas cylinders of composite construction—Specification and test methods—Part 3: Fully wrapped fibre reinforced composite gas cylinders with non-load-sharing metallic or non-metallic liners, First edition, September 2002; into § 178.71.

(60) ISO 11119–3:2013(E), Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 3: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 l with non-load-sharing metallic or non-metallic liners, Second edition, 2013–04–15; into §§ 178.71; 178.75.

(61) ISO 11119–4:2016(E), Gas cylinders—Refillable composite gas cylinders—Design, construction and testing—Part 4: Fully wrapped fibre reinforced composite gas cylinders up to 150 L with load-sharing welded metallic liners, First Edition, 2016–02–15; into § 178.71; 178.75.

(62) ISO 11120(E), Gas cylinders—Refillable seamless steel tubes of water capacity between 150 l and 3000 l—Design, construction and testing, First edition, 1999–03; into §§ 178.71; 178.75.

(63) ISO 11120:2015(E), Gas cylinders—Refillable seamless steel tubes of water capacity between 150 l and 3000 l—Design, construction and testing, Second Edition, 2015–02–01; into §§ 178.71; 178.75.

(64) ISO 11513:2011(E), Gas cylinders—Refillable welded steel cylinders containing materials for sub-atmospheric gas packaging (excluding acetylene)—Design, construction, testing, use and periodic inspection, First edition, 2011–09–12; into §§ 173.302c; 178.71; 180.207.

(65) ISO 11621(E), Gas cylinders—Procedures for change of gas service, First edition, April 1997; into §§ 173.302, 173.336, 173.337.

(66) ISO 11623(E), Transportable gas cylinders—Periodic inspection and testing of composite gas cylinders, First edition, March 2002; into § 180.207.

(67) ISO 11623(E):2015, Gas cylinders—Composite construction—Periodic inspection and testing, Second edition, 2015–12–01; into § 180.207.

(68) ISO 13340:2001(E), Transportable gas cylinders—Cylinder valves for non-refillable cylinders—Specification and prototype testing, First edition, 2004–04–01; into §§ 173.301b; 178.71.

(69) ISO 13736:2008(E), Determination of flash point—Abel closed-cup method, Second Edition, 2008–09–15; into § 173.120.

(70) ISO 14246:2014(E), Gas cylinders—Cylinder valves—Manufacturing tests and examination, Second Edition, 2014–06–15; into § 178.71.

(71) ISO 14246:2014/Amd 1:2017(E), Gas cylinders—Cylinder valves—Manufacturing tests and examinations—Amendment 1, Second Edition, 2017–06; into § 178.71.

(72) ISO 16111:2008(E), Transportable gas storage devices—Hydrogen absorbed in reversible metal hydride, First Edition, 2008–11–15; into §§ 173.301b; 173.311; 178.71.

(73) ISO 16148:2016(E), Gas cylinders—Refillable seamless steel gas cylinders and tubes—Acoustic emission examination (AT) and follow-up ultrasonic examination (UT) for periodic inspection and testing, Second Edition, 2016–04–15; into § 180.207.

(74) ISO 17871:2015(E), Gas cylinders—Quick-release cylinder valves—Specification and type testing, First Edition, 2015–08–15; into § 173.301b.

(75) ISO 17879: 2017(E), Gas cylinders—Self-closing cylinder valves—Specification and type testing, First Edition, 2017–07; into §§ 173.301b;178.71.

(76) ISO 18172–1:2007(E), Gas cylinders—Refillable welded stainless steel cylinders—Part 1: Test pressure 6 MPa and below, First Edition, 2007–03–01; into § 178.71.

(77) ISO 20475:2018(E), Gas cylinders—Cylinder bundles—Periodic inspection and testing, First Edition, 2018–02; into § 180.207.

(78) ISO 20703:2006(E), Gas cylinders—Refillable welded aluminum-alloy cylinders—Design, construction and testing, First Edition, 2006–05–01; into § 178.71.

(79) ISO 21172–1:2015(E), Gas cylinders—Welded steel pressure drums up to 3000 litres capacity for the transport of gases—Design and construction—Part 1: Capacities up to 1000 litres, First edition, 2015–04–01; into § 178.71.

(80) ISO 22434:2006(E), Transportable gas cylinders—Inspection and maintenance of cylinder valves, First Edition, 2006–09–01; into § 180.207.

(81) ISO/TR 11364:2012(E), Gas cylinders—Compilation of national and international valve stem/gas cylinder neck threads and their identification and marking system, First Edition, 2012–12–01; into § 178.71.

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(aa) Organization for Economic Cooperation and Development (OECD), OECD Publications and Information Center, 2001 L Street NW, Suite 700, Washington, DC 20036; (+33 1 45 24 82 00, *https://www.oecd.org/*).

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(3) OECD Guideline for the Testing of Chemicals 431 (Test No. 431): In vitro skin corrosion: reconstructed human epidermis (RHE) test method, adopted 29 July 2016; into § 173.137.

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(dd) * * *

(1) Recommendations on the Transport of Dangerous Goods, Model Regulations (UN Recommendations), 21st revised edition, copyright 2019; into §§ 171.8; 171.12; 172.202; 172.401; 172.407; 172.502; 172.519; 173.22; 173.24; 173.24b; 173.40; 173.56; 173.192; 173.302b; 173.304b; 178.75; 178.274; as follows:

(i) Volume I, ST/SG/AC.10.1/21/Rev.21 (Vol. I).

(ii) Volume II, ST/SG/AC.10.1/21/Rev.21 (Vol. II).

(2) Manual of Tests and Criteria (UN Manual of Tests and Criteria), 7th revised edition, ST/SG/AC.10/11/Rev.7, copyright 2019; into §§ 171.24, 172.102; 173.21; 173.56 through 173.58; 173.60; 173.115; 173.124; 173.125; 173.127; 173.128; 173.137; 173.185; 173.220; 173.221; 173.224; 173.225; 173.232; part 173, appendix H; 175.10; 176.905; 178.274.

(3) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 8th revised edition, ST/SG/AC.10/30/Rev.8, copyright 2019; into § 172.401.

(4) Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), copyright 2020; into § 171.23; as follows:

(i) Volume I, ECE/TRANS/300 (Vol. I).

(ii) Volume II, ECE/TRANS/300 (Vol. II).

(iii) Corrigendum, ECE/TRANS/300 (Corr. 1).

* * * * *

■ 3. In § 171.8, revise the definitions for ''SADT'' and ''SAPT'' to read as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

SADT means self-accelerated decomposition temperature and is the lowest temperature at which self-accelerating decomposition may occur in a substance in the packaging, IBC, or portable tank offered for transport. *See* also § 173.21(f) of this subchapter.

* * * * *

SAPT means self-accelerated polymerization temperature and is the lowest temperature at which self-accelerating polymerization may occur with a substance in the packaging, IBC, or portable tank as offered for transport. *See* also § 173.21(f) of this subchapter. This definition will be effective until January 2, 2023.

* * * * *

■ 4. In § 171.12, revise paragraph (a)(1) to read as follows:

§ 171.12 North American Shipments.

(a) * * *

(1) *Applicability.* A hazardous material transported from Canada to the United States, from the United States to Canada, or transiting the United States to Canada or a foreign destination may be offered for transportation or transported by motor carrier and rail in accordance with the Transport Canada TDG Regulations (IBR, *see* § 171.7), an equivalency certificate (permit for equivalent level of safety), or a temporary certificate (permit in support of public interest) issued by Transport Canada as an alternative to the TDG Regulations, as authorized in § 171.22, provided the requirements in §§ 171.22 and 171.23, as applicable, and this section are met. In addition, a cylinder, pressure drum, MEGC, cargo tank motor vehicle, portable tank or rail tank car authorized by the Transport Canada TDG Regulations may be used for transportation to, from, or within the United States provided the cylinder, pressure drum, MEGC, cargo tank motor vehicle, portable tank, or rail tank car conforms to the applicable requirements of this section. Except as otherwise provided in this subpart and subpart C of this part, the requirements in parts 172, 173, and 178 of this subchapter do not apply for a material transported in accordance with the Transport Canada TDG Regulations.

* * * * *

■ 5. In § 171.23, revise paragraph (a)(3) introductory text to read as follows:

§ 171.23 Requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Transport Canada TDG Regulations, or the IAEA Regulations.

* * * * *

(a) * * *

(3) *Pi-marked pressure receptacles.* Pressure receptacles that are marked with a pi mark in accordance with the European Directive 2010/35/EU (IBR, *see* § 171.7) on transportable pressure equipment (TPED) and that comply with the requirements of Packing Instruction P200 or P208 and 6.2 of the ADR (IBR, *see* § 171.7) concerning pressure relief device use, test period, filling ratios, test pressure, maximum working pressure, and material compatibility for the lading contained or gas being filled, are authorized as follows:

* * * * *

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 6. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 7. In § 172.101, The Hazardous Materials Table is amended by removing the entries under ''[REMOVE],'' by adding in alphabetical order the entries under ''[ADD,]'' and by revising entries under ''[REVISE]'' in the appropriate alphabetical sequence.

The additions and revisions read as follows:

§ 172.101 Purpose and use of the hazardous materials table.

* * * * *

BILLING CODE 4910–60–P

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification Numbers	PG	Label Codes	Special Provisions (§ 172.102)	(8) Packaging (§ 173.***)			(9) Quantity limitations (*see* §§ 173.27 and 175.75)		(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	[REMOVE]												
	*		*		*		*		*		*		*
	Battery-powered vehicle or Battery-powered equipment	9	UN3171		9	134	220	220	None	No limit	No limit	A	
	*		*		*		*		*		*		*
	Dangerous Goods in Machinery *or* Dangerous Goods in Apparatus	9	UN3363			136, A105	None	222	None	*See* A105	*See* A105	A	
	*		*		*		*		*		*		*
	2-Dimethylaminoethyl methacrylate	6.1	UN2522	II	6.1	IB2, T7, TP2	153	202	243	5 L	60 L	B	40
	Fuel system components (including fuel control units (FCU), carburetors, fuel lines, fuel pumps) see Dangerous Goods in Apparatus *or* Dangerous Goods in Machinery												
	Regulated medical waste, n.o.s. *or* Clinical waste, unspecified, n.o.s. *or* (BIO) Medical waste, n.o.s. *or* Biomedical waste, n.o.s., *or* Medical Waste n.o.s.	6.2	UN3291	II	6.2	41, 337, A13	134	197	197	No limit	No limit	B	40
	*		*		*		*		*		*		*
	[ADD]												
	*		*		*		*		*		*		*
	Battery-powered vehicle *or* Battery-powered equipment	9	UN3171		9	134, 360	220	220	None	No limit	No limit	A	
	*		*		*		*		*		*		*
	Dangerous goods in articles *or* Dangerous goods in machinery *or* Dangerous goods in apparatus	9	UN3363			136, A105	None	222	None	*See* A105	*See* A105	A	
	*		*		*		*		*		*		*
	Detonators, electronic *programmable for blasting*	1.1B	UN0511		1.1B	148	63(f), 63(g)	62	None	Forbidden	Forbidden	05	25
	Detonators, electronic *programmable for blasting*	1.4B	UN0512		1.4B	103	63(f), 63(g)	62	None	Forbidden	75 kg	05	25

	Detonators, electronic *programmable for blasting*	1.4S	UN0513		1.4S	148, 347	63(f), 63(g)	62	None	25 kg	100 kg	01	25
	*		*		*		*		*		*		*
	2-Dimethylaminoethyl methacrylate, stabilized	6.1	UN2522	II	6.1	387, IB2, T7, TP2	153	202	243	5 L	60 L	B	40
	*		*		*		*		*		*		*
	Fuel system components (including fuel control units (FCU), carburetors, fuel lines, fuel pumps) see Dangerous Goods in Apparatus *or* Dangerous Goods in Articles *or* Dangerous Goods in Machinery												
	Medical waste, category A, affecting humans*, solid or* Medical waste, category A, affecting animals *only, solid*	6.2	UN3549		6.2	131, 430							
	Regulated medical waste, n.o.s. *or* Clinical waste, unspecified, n.o.s. *or* (BIO) Medical waste, n.o.s. *or* Biomedical waste, n.o.s., *or* Medical Waste n.o.s.	6.2	UN3291		6.2	41, 337, A13	134	197	197	No limit	No limit	B	40
	*		*		*		*		*		*		*
	[REVISE]												
	*		*		*		*		*		*		*
	Aerosols, *corrosive, Packing Group II or III, (each not exceeding 1 L capacity)*	2.2	UN1950		2.2, 8	A34	306	None	None	75 kg	150 kg	A	25, 87, 126, 157
	Aerosols, *flammable, (each not exceeding 1 L capacity)*	2.1	UN1950		2.1	N82	306	None	None	75 kg	150 kg	A	25, 87, 126, 157
	Aerosols, flammable, n.o.s. *(engine starting fluid) (each not exceeding 1 L capacity)*	2.1	UN1950		2.1	N82	306	304	None	Forbidden	150 kg	A	25, 87, 126, 157
	Aerosols, *non-flammable, (each not exceeding 1 L capacity)*	2.2	UN1950		2.2		306	None	None	75 kg	150 kg	A	25, 87, 126, 157
	Aerosols, *poison, Packing Group III (each not exceeding 1 L capacity)*	2.2	UN1950		2.2, 6.1		306	None	None	Forbidden	Forbidden	A	25, 87, 126, 157
	*		*		*		*		*		*		*
G	Alcoholates solution, n.o.s., *in alcohol*	3	UN3274	II	3, 8	IB2	150	202	243	1 L	5 L	B	52
	*		*		*		*		*		*		*

G	Alkali metal alcoholates, self-heating, corrosive, n.o.s.	4.2	UN3206	II	4.2, 8	64, A7, IB5, IP2, T3, TP33, W31	None	212	242	15 kg	50 kg	B	52
				III	4.2, 8	64, A7, IB8, IP3, T1, TP33, W31	None	213	242	25 kg	100 kg	B	52
	*		*		*		*		*		*		*
G	Articles containing a substance liable to spontaneous combustion, n.o.s.	4.2	UN3542		4.2	131, 391	None	214	214	Forbidden	Forbidden		
G	Articles containing a substance which in contact with water emits flammable gases, n.o.s.	4.3	UN3543		4.3	131, 391	None	214	214	Forbidden	Forbidden		
G	Articles containing corrosive substance, n.o.s.	8	UN3547		8	391	None	232	232	Forbidden	Forbidden	B	
G	Articles containing flammable gas, n.o.s.	2.1	UN3537		2.1	391	None	232	232	Forbidden	Forbidden	D	
G	Articles containing flammable liquid, n.o.s.	3	UN3540		3	391	None	232	232	Forbidden	Forbidden	B	
G	Articles containing flammable solid, n.o.s.	4.1	UN3541		4.1	391	None	232	232	Forbidden	Forbidden	B	
G	Articles containing miscellaneous dangerous goods, n.o.s.	9	UN3548		9	391	None	232	232	Forbidden	Forbidden	A	
G	Articles containing non-flammable, non-toxic gas, n.o.s.	2.2	UN3538		2.2	391	None	232	232	Forbidden	Forbidden	A	
G	Articles containing organic peroxide, n.o.s.	5.2	UN3545		5.2	131, 391	None	214	214	Forbidden	Forbidden		
G	Articles containing oxidizing substance, n.o.s.	5.1	UN3544		5.1	131, 391	None	214	214	Forbidden	Forbidden		
G	Articles containing toxic gas, n.o.s.	2.3	UN3539		2.3	131, 391	None	214	214	Forbidden	Forbidden		
G	Articles containing toxic substance, n.o.s.	6.1	UN3546		6.1	391	None	232	232	Forbidden	Forbidden	B	
	*		*		*		*		*		*		*
G	Desensitized explosives, solid, n.o.s.	4.1	UN3380	I	4.1	164, 197	None	211	None	Forbidden	Forbidden	D	28, 36
	*		*		*		*		*		*		*
	Dimethyl disulfide	3	UN2381	II	3, 6.1	IB2, T7, TP2, TP13	150	202	242	Forbidden	Forbidden	B	40
	*		*		*		*		*		*		*
G	Environmentally hazardous substance, liquid, n.o.s.	9	UN3082	III	9	8, 146, 173, 335, 441, IB3, T4, TP1, TP29	155	203	241	No limit	No limit	A	
G	Environmentally hazardous substance, solid, n.o.s.	9	UN3077	III	9	8, 146, 335, 384, 441, A112,	155	213	240	No limit	No limit	A	

						B54, B120, IB8, IP3, N20, N91, T1, TP33							
	*		*		*		*		*		*		*
A, I, W	Fibers, vegetable, dry	4.1	UN3360	III	4.1	137	151	213	240	Forbidden	Forbidden	A	
	*		*		*		*		*		*		*
A, W	Fish meal, stabilized *or* Fish scrap, stabilized	9	UN2216	III		155, IB8, IP3, T1, TP33	155	218	218	100 kg	200 kg	B	25, 88, 122, 128
	*		*		*		*		*		*		*
	Gas cartridges, *(flammable) without a release device, non-refillable*	2.1	UN2037		2.1		306	304	None	1 kg	15 kg	B	40, 157
	*		*		*		*		*		*		*
G	Infectious substances, affecting animals *only*	6.2	UN2900		6.2	A82	134	196	None	50 mL or 50 g	4 L or 4 kg	E	13, 40, 95, 155
G	Infectious substances, affecting humans	6.2	UN2814		6.2	A82	134	196	None	50 mL or 50 g	4 L or 4 kg	E	13, 40, 95, 155
	*		*		*		*		*		*		*
	Lithium ion batteries *including lithium ion polymer batteries*	9	UN3480		9	388, 422, A54, A100	185	185	185	Forbidden	35 kg	A	156
	Lithium ion batteries contained in equipment *including lithium ion polymer batteries*	9	UN3481		9	181, 360, 388, 422, A54	185	185	185	5 kg	35 kg	A	156
	Lithium ion batteries packed with equipment *including lithium ion polymer batteries*	9	UN3481		9	181, 360, 388, 422, A54	185	185	185	5 kg	35 kg	A	156
	Lithium metal batteries *including lithium alloy batteries*	9	UN3090		9	388, 422, A54	185	185	185	Forbidden	35 kg	A	156
	Lithium metal batteries contained in equipment *including lithium alloy batteries*	9	UN3091		9	181, 360, 388, 422, A54, A101	185	185	185	5 kg	35 kg	A	156
	Lithium metal batteries packed with equipment *including lithium alloy batteries*	9	UN3091		9	181, 360, 388, 422, A54	185	185	185	5 kg	35 kg	A	156
	*		*		*		*		*		*		*
	Nitrocellulose, *dry or wetted with less than 25 percent water (or alcohol), by mass*	1.1D	UN0340		1.1D	196	None	62	None	Forbidden	Forbidden	04	25, 27E

	Nitrocellulose, *with not more than 12.6 percent nitrogen, by dry mass* mixture with *or* without plasticizer, with *or* without pigment	4.1	UN2557	II	4.1	44, 197, W31	151	212	None	1 kg	15 kg	D	28, 36
	*		*		*		*		*		*		*
	Nitrocellulose, plasticized *with not less than 18 percent plasticizing substance, by mass*	1.3C	UN0343		1.3C	196	None	62	None	Forbidden	Forbidden	04	25
	*		*		*		*		*		*		*
	Nitrocellulose, *unmodified or plasticized with less than 18 percent plasticizing substance, by mass*	1.1D	UN0341		1.1D	196	None	62	None	Forbidden	Forbidden	04	25, 27E
	Nitrocellulose, wetted *with not less than 25 percent alcohol, by mass*	1.3C	UN0342		1.3C	196	None	62	None	Forbidden	Forbidden	04	25
	Nitrocellulose with alcohol *with not less than 25 percent alcohol by mass, and with not more than 12.6 percent nitrogen, by dry mass*	4.1	UN2556	II	4.1	197, W31	151	212	None	1 kg	15 kg	D	12, 25, 28, 36
	Nitrocellulose with water *with not less than 25 percent water, by mass*	4.1	UN2555	II	4.1	197, W31	151	212	None	15 kg	50 kg	E	28, 36
	*		*		*		*		*		*		*
	Receptacles, small, containing gas *or* gas cartridges *(flammable) without release device, not refillable and not exceeding 1 L capacity*	2.1	UN2037		2.1		306	304	None	1 kg	15 kg	B	40, 157
	Receptacles, small, containing gas *or* gas *cartridges (non-flammable) without release device, not refillable and not exceeding 1 L capacity*	2.2	UN2037		2.2		306	304	None	1 kg	15 kg	B	40, 157
	Receptacles, small, containing gas *or* gas cartridges *(oxidizing), without release device, not refillable and not exceeding 1 L capacity*	2.2	UN2037		2.2, 5.1	, A14	306	304	None	1 kg	15 kg	B	40, 157
	*		*		*		*		*		*		*
	Sodium methylate	4.2	UN1431	II	4.2, 8	A7, A19, IB5, IP2, T3, TP33, W31	None	212	242	15 kg	50 kg	B	52

	Sodium methylate solutions *in alcohol*	3	UN1289	II	3, 8	IB2, T7, TP1, TP8	150	202	243	1 L	5 L	B	52
				III	3, 8	B1, IB3, T4, TP1	150	203	242	5 L	60 L	A	52
	*		*		*		*		*		*		*
G	Water-reactive liquid, corrosive, n.o.s.	4.3	UN3129	I	4.3, 8	T14, TP2, TP7, TP13	None	201	243	Forbidden	1 L	D	13,148
				II	4.3, 8	IB1, T11, TP2, TP7	None	202	243	1 L	5 L	E	13, 85, 148
				III	4.3, 8	IB2, T7, TP2, TP7	None	203	242	5 L	60 L	E	13, 85, 148
	*		*		*		*		*		*		*
G	Water-reactive solid, flammable, n.o.s.	4.3	UN3132	I	4.3, 4.1	IB4, N40, W31	None	211	242	Forbidden	15 kg	D	13, 148
	\			II	4.3, 4.1	IB4, T3, TP33, W31, W40	151	212	242	15 kg	50 kg	E	13, 85, 148
				III	4.3, 4.1	IB6, T1, TP33, W31	151	213	241	25 kg	100 kg	E	13, 85, 148
	*		*		*		*		*		*		*
G	Water-reactive solid, self-heating, n.o.s.	4.3	UN3135	I	4.3, 4.2	N40, W31	None	211	242	Forbidden	15 kg	D	13, 148
				II	4.3, 4.2	IB5, IP2, T3, TP33, W31, W40	None	212	242	15 kg	50 kg	E	13, 85, 148
				III	4.3, 4.2	IB8, IP4, T1, TP33, W31	None	213	241	25 kg	100 kg	E	13, 85, 148
	*		*		*		*		*		*		*
G	Water-reactive liquid, n.o.s.	4.3	UN3148	I	4.3	T13, TP2, TP7, W31	None	201	244	Forbidden	1 L	E	13, 40, 148
				II	4.3	IB1, T7, TP2, TP7, W31	None	202	243	1 L	5 L	E	13, 40, 148
	Water-reactive liquid, n.o.s.			III	4.3	IB2, T7, TP2, TP7, W31	None	203	242	5 L	60 L	E	13, 40, 148
	*		*		*		*		*		*		*

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* * * * *

■ 8. In § 172.102:

■ a. In paragraph (c)(1):

■ i. Revise special provisions 47, 134, 135, 136, and 147;

■ ii. Add special provisions 196 and 197 in numerical order;

■ iii. Revise special provisions 360, 370, and 379d(1); and

■ iv. Add special provisions 430 and 441 in numerical order.

■ b. In paragraph (c)(8)(ii), remove and reserve TP codes TP39 and TP41.

The additions and revisions read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(1) * * *

47 Mixtures of solids that are not subject to this subchapter and flammable liquids may be transported under this entry without first applying the classification criteria of Division 4.1, provided there is no free liquid visible at the time the material is loaded or at the time the packaging or transport unit is closed. Except when the liquids are fully absorbed in solid material contained in sealed bags, for single packagings, each packaging must correspond to a design type that has passed a leakproofness test at the Packing Group II level. Sealed packets and articles containing less than 10 mL of a Class 3 liquid in Packing Group II or III absorbed onto a solid material are not subject to this subchapter provided there is no free liquid in the packet or article.

* * * * *

134 This entry applies only to vehicles powered by wet batteries, sodium batteries, lithium metal batteries or lithium ion batteries, and equipment powered by wet batteries or sodium batteries that are transported with these batteries installed. Lithium batteries installed in a cargo transport unit, designed only to provide power external to the transport unit must use the proper shipping name ''Lithium batteries installed in cargo transport unit'' found in the § 172.101 Hazardous Materials Table.

a. For the purpose of this special provision, vehicles are self-propelled apparatus designed to carry one or more persons or goods. Examples of such vehicles are electrically-powered cars, motorcycles, scooters, three- and four-wheeled vehicles or motorcycles, trucks, locomotives, bicycles (pedal cycles with an electric motor) and other vehicles of this type (*e.g.,* self-balancing vehicles or vehicles not equipped with at least one seating position), lawn tractors, self-propelled farming and construction equipment, boats, aircraft, wheelchairs and other mobility aids. This includes vehicles transported in a packaging. In this case, some parts of the vehicle may be detached from its frame to fit into the packaging.

b. Examples of equipment are lawnmowers, cleaning machines, or model boats and model aircraft. Equipment powered by lithium metal batteries or lithium ion batteries must be described using the entries ''Lithium metal batteries contained in equipment'' or ''Lithium metal batteries packed with equipment'' or ''Lithium ion batteries contained in equipment'' or ''Lithium ion batteries packed with equipment,'' as appropriate.

c. Self-propelled vehicles or equipment that also contain an internal combustion engine must be described using the entries ''Engine, internal combustion, flammable gas powered'' or ''Engine, internal combustion, flammable liquid powered'' or ''Vehicle, flammable gas powered'' or ''Vehicle, flammable liquid powered,'' as appropriate. These entries include hybrid electric vehicles powered by both an internal combustion engine and batteries. Additionally, self-propelled vehicles or equipment that contain a fuel cell engine must be described using the entries ''Engine, fuel cell, flammable gas powered'' or ''Engine, fuel cell, flammable liquid powered'' or ''Vehicle, fuel cell, flammable gas powered'' or ''Vehicle, fuel cell, flammable liquid powered,'' as appropriate. These entries include hybrid electric vehicles powered by a fuel cell engine, an internal combustion engine, and batteries.

135 Internal combustion engines installed in a vehicle must be described using ''Vehicle, flammable gas powered'' or ''Vehicle, flammable liquid powered,'' as appropriate. If a vehicle is powered by a flammable liquid and a flammable gas internal combustion engine, it must be described using ''Vehicle, flammable gas powered.'' This includes hybrid electric vehicles powered by both an internal combustion engine and wet, sodium or lithium batteries installed. If a fuel cell engine is installed in a vehicle, the vehicle must be described using ''Vehicle, fuel cell, flammable gas powered'' or ''Vehicle, fuel cell, flammable liquid powered,'' as appropriate. This includes hybrid electric vehicles powered by a fuel cell, an internal combustion engine, and wet, sodium or lithium batteries installed. For the purpose of this special provision, vehicles are self-propelled apparatus designed to carry one or more persons or goods. Examples of such vehicles are cars, motorcycles, trucks, locomotives, scooters, three- and four-wheeled vehicles or motorcycles, lawn tractors, self-propelled farming and construction equipment, boats, and aircraft. Furthermore, lithium batteries installed in a cargo transport unit, designed only to provide power external to the transport unit must be described using the proper shipping name ''Lithium batteries installed in cargo transport unit'' found in the § 172.101 Hazardous Materials Table.

136 This entry applies only to articles, machinery, and apparatus containing hazardous materials as an integral element of the article, machinery, or apparatus. It may not be used to describe articles, machinery, or apparatus for which a proper shipping name exists in the § 172.101 Table. Except when approved by the Associate Administrator, these items may only contain hazardous materials for which exceptions are referenced in Column (8) of the § 172.101 Table and are provided in part 173, subparts D and G, of this subchapter. Hazardous materials shipped under this entry are excepted from the labeling requirements of this subchapter unless offered for transportation or transported by aircraft and are not subject to the placarding requirements of subpart F of this part. Orientation markings as described in § 172.312(a)(2) are required when liquid hazardous materials may escape due to incorrect orientation. The article, machinery, or apparatus, if unpackaged, or the packaging in which it is contained shall be marked ''Dangerous goods in articles'' or ''Dangerous goods in machinery'' or ''Dangerous goods in apparatus'' as appropriate, with the identification number UN3363. For transportation by aircraft, articles, machinery, or apparatus, may not contain any material forbidden for transportation by passenger or cargo aircraft. The Associate Administrator may except from the requirements of this subchapter articles, machinery, and apparatus provided:

a. It is shown that it does not pose a significant risk in transportation;

b. The quantities of hazardous materials do not exceed those specified in § 173.4a of this subchapter; and

c. The equipment, and machinery or apparatus articles conforms with § 173.222 of this subchapter.

* * * * *

147 This entry applies to non-sensitized emulsions, suspensions, and gels consisting primarily of a mixture of ammonium nitrate and fuel, intended to produce a Type E blasting explosive only after further processing prior to use. The mixture for emulsions typically has the following composition: 60–85% ammonium nitrate; 5–30% water; 2–8% fuel; 0.5–4% emulsifier or thickening agent; 0–10% soluble flame suppressants; and trace additives. Other inorganic nitrate salts may replace part of the ammonium nitrate. The mixture for suspensions and gels typically has the following composition: 60–85% ammonium nitrate; 0–5% sodium or

potassium perchlorate; 0–17% hexamine nitrate or monomethylamine nitrate; 5–30% water; 2–15% fuel; 0.5–4% thickening agent; 0–10% soluble flame suppressants; and trace additives. Other inorganic nitrate salts may replace part of the ammonium nitrate. These substances must satisfy the criteria for classification as an ammonium nitrate emulsion of Test Series 8 of the UN Manual of Tests and Criteria, Part I, Section 18 (IBR, *see* § 171.7 of this subchapter), and may not be classified and transported unless approved by the Associate Administrator.

* * * * *

196 The nitrocellulose must meet the criteria of the Bergmann-Junk test or methyl violet paper test in the UN Manual of Tests and Criteria, Appendix 10 (IBR, *see* § 171.7 of this subchapter). Test of type 3(c) is not required.

197 The nitrocellulose must meet the criteria of the Bergmann-Junk test or methyl violet paper test in the UN Manual of Tests and Criteria, Appendix 10 (IBR, *see* § 171.7 of this subchapter).

* * * * *

360 Vehicles powered only by lithium batteries must be described using ''UN3171, Battery-powered vehicle.'' Lithium batteries installed in a cargo transport unit, designed only to provide power external to the transport unit, must be described using ''UN3536, Lithium batteries installed in a cargo transport unit.''

* * * * *

370 This entry also applies to ammonium nitrate with not more than 0.2% combustible substances, including any organic substance calculated as carbon, to the exclusion of any added substance, that gives a positive result when tested in accordance with Test Series 2 of the UN Manual of Tests and Criteria, Part I (IBR; see § 171.7 of this subchapter). *See also* UN1942 in the § 172.101 Hazardous Materials Table. This entry may not be used for ammonium nitrate for which a proper shipping name already exists in the § 172.101 Hazardous Materials Table, including ammonium nitrate mixed with fuel oil or any other commercial grade of ammonium nitrate (*e.g.,* ammonium nitrate fertilizer).

* * * * *

379 * * *

d. * * *

(1) Receptacles shall be made of a material compatible with ammonia as specified in ISO 11114–1:2012(E) and ISO 11114–1:2012/Amd 1:2017(E) (IBR, *see* § 171.7 of this subchapter);

* * * * *

430 This entry shall only be used for solid medical waste of Category A transported for disposal.

* * * * *

441 For marine pollutants transported under ''UN3077, Environmentally hazardous substance, solid, n.o.s.'' or ''UN3082, Environmentally hazardous substance, liquid, n.o.s.'' and for purposes of shipping paper and package marking requirements, the technical name used in association with the basic description may be a proper shipping name listed in the § 172.101 Hazardous Material Table; provided that the name chosen is not also an entry that includes ''n.o.s.'' as a part of the name or one that has a ''G'' in column (1) of the table.

* * * * *

■ 9. In § 172.203, revise the first sentence of paragraph (i)(2), add paragraph (i)(4), revise paragraph (l)(1), and add paragraph (q) to read as follows:

§ 172.203 Additional description requirements.

* * * * *

(i) * * *

(2) A minimum flashpoint, if 60 °C (140 °F) or below (in °C closed cup (c.c.)), in association with the basic description, for Class 3 flammable liquid materials (as a primary or subsidiary hazard). * * *

* * * * *

(4) For lithium cells or batteries transported in accordance with § 173.185(f), ''DAMAGED/DEFECTIVE''; and for lithium cells or batteries transported for purposes of disposal or recycling, ''LITHIUM BATTERIES FOR DISPOSAL'' or ''LITHIUM BATTERIES FOR RECYCLING'', as appropriate.

* * * * *

(l) * * *

(1) For a proper shipping name used to describe a hazardous material that is a marine pollutant, either assigned the letter ''G'' in column (1) of the § 172.101 hazardous materials table, or that contains the text ''n.o.s.'', the name of the component that makes the material a marine pollutant must appear in parentheses in association with the basic description. Where two or more components that make the material a marine pollutant are present, the names of at least two of the components most predominantly contributing to the marine pollutant designation must appear in parentheses in association with the basic description. For material described using ''UN3077, Environmentally hazardous substance, solid, n.o.s.'' and ''UN3082, Environmentally hazardous substance, liquid, n.o.s.,'' *see* § 172.102(c)(1), special provision 441 for additional provisions.

* * * * *

(q) *Holding time.* The date at which the actual holding time ends, as calculated in accordance with § 178.338–9, must be provided on the shipping paper in association with the basic description for refrigerated liquefied gases transported in a portable tank.

■ 10. In § 172.301, revise paragraph (a)(1) introductory text to read as follows:

§ 172.301 General marking requirements for non-bulk packagings.

(a) * * *

(1) Except as otherwise provided by this subchapter, each person who offers a hazardous material for transportation in a non-bulk packaging must mark the package with the proper shipping name and identification number (preceded by ''UN'', ''NA'' or ''ID,'' as appropriate), as shown in the § 172.101 Hazardous Materials Table. The identification number marking preceded by ''UN'', ''NA'', or ''ID'' as appropriate must be marked in characters at least 12 mm (0.47 inches) high. Packages with a maximum capacity of 30 liters (8 gallons) or less, 30 kg (66 pounds) maximum net mass, or cylinders with a water capacity of 60 liters (16 gallons) or less must be marked with characters at least 6 mm (0.24 inches) high. Packages with a maximum capacity of 5 liters (1.32 gallons) or less or 5 kg maximum net mass (11 pounds) or less must be marked in a size appropriate for the size of the package.

* * * * *

■ 11. In § 172.315, add paragraph (b)(3) to read as follows:

§ 172.315 Limited quantities.

* * * * *

(b) * * *

(3) For transportation by aircraft, the entire mark must appear on one side of the package.

* * * * *

■ 12. In § 172.322, revise paragraph (a)(1) to read as follows:

§ 172.322 Marine pollutants.

(a) * * *

(1) For a proper shipping name used to describe a hazardous material that is a marine pollutant and assigned the letter ''G'' in column (1) of the § 172.101 hazardous materials table or that contains the text ''n.o.s.,'' the name of the component which makes the material a marine pollutant must be marked on the package in parentheses

in association with the marked proper shipping name unless the proper shipping name identifies by name the component which makes the material a marine pollutant. Where two or more components that make a material a marine pollutant are present, the names of at least two of the components most predominantly contributing to the marine pollutant designation must appear in parentheses in association with the marked proper shipping name. For materials described using ''UN3077, Environmentally hazardous substance, solid, n.o.s.'' and ''UN3082, Environmentally hazardous substance, liquid, n.o.s.,'' *see* § 172.102(c)(1), special provision 441 for additional provisions; and

* * * * *

■ 13. In § 172.406, revise paragraph (a) to read as follows:

§ 172.406 Placement of labels.

(a) *General.* (1) Except as provided in paragraphs (b) and (e) of this section, each label required by this subpart must—

(i) Be printed on or affixed to a surface (other than the bottom) of the package or containment device containing the hazardous material;

(ii) Be located on the same surface of the package and near the proper shipping name marking, if the package dimensions are adequate; and

(iii) For transportation by aircraft, the entire label(s) must appear on one side of the package. For cylindrical packages, the label must be of such dimensions that it will not overlap itself. In the case of cylindrical packages containing radioactive materials, which require two identical labels, these labels must be centered on opposite points of the circumference and must not overlap each other. If the dimensions of the package are such that two identical labels cannot be affixed without overlapping each other, one label is acceptable provided it does not overlap itself.

(2) Except as provided in paragraph (e) of this section, duplicate labeling is not required on a package or containment device (such as to satisfy redundant labeling requirements).

* * * * *

§ 172.447 [Amended]

■ 14. In § 172.447, remove paragraph (c).

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 15. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 16. In § 173.4a, redesignate paragraph (g)(3) as paragraph (g)(4) and add new paragraph (g)(3) to read as follows:

§ 173.4a Excepted quantities.

* * * * *

(g) * * *

(3) For transportation by aircraft, the entire mark must appear on one side of the package.

* * * * *

■ 17. Add § 173.14 to subpart A to read as follows:

§ 173.14 Hazardous materials in equipment in use or intended for use during transport.

(a) Except for transportation by aircraft, hazardous materials (*e.g.,* lithium batteries, fuel cell cartridges) contained in equipment, such as data loggers and cargo tracking devices, attached to or placed in packages, overpacks, or containers are not subject to this subchapter other than the following:

(1) The equipment must be in use or intended for use during transportation;

(2) The hazardous materials (*e.g.,* lithium batteries, fuel cell cartridges) must meet the applicable construction and test requirements specified in this subchapter;

(3) The equipment must be capable of withstanding the shocks and loadings normally encountered during transport and must be safe for use in the environments to which it may be exposed; and

(4) When offered for transport by vessel, the requirements in § 176.76(a)(9) of this subchapter apply.

(b) For transportation by aircraft, lithium batteries contained in equipment such as data loggers and cargo tracking devices, attached to or placed in packages containing COVID–19 pharmaceuticals, are not subject to the marking and documentation requirements of § 173.185(c)(3) and (c)(4)(iv). This same package, when shipped without the COVID–19 pharmaceuticals for the purpose of use or reuse, is also not subject to the marking and documentation requirements of § 173.185(c)(3) and (c)(4)(iv), as applicable, provided prior arrangements have been made with the operator.

(c) The exception provided by this section does not apply to hazardous materials shipped as cargo. Hazardous materials contained in equipment as described in this section, when transported as a cargo, are subject to, and must be transported in accordance with, all applicable requirements of this subchapter.

■ 18. In § 173.27, revise paragraph (c)(2), add paragraph (f) introductory text, and revise paragraph (f)(1), tables 1 and 2 to paragraph (f), and the heading to table 3 to paragraph (f) to read as follows:

§ 173.27 General requirements for transportation by aircraft.

* * * * *

(c) * * *

(2) Except for packagings used for material transported as ''UN3082, Environmentally hazardous substance, liquid, n.o.s.,'' packagings for which retention of liquid is a basic function must be capable of withstanding without leakage the greater of—

* * * * *

(f) *Combination packagings.* Unless otherwise specified in this part, or in Subpart C of part 171 of this subchapter, when combination packagings are intended for transportation aboard an aircraft, inner packagings must conform to the quantity limitations set forth in Table 1 of this paragraph for transport aboard passenger-carrying aircraft and Table 2 of this paragraph for transport aboard cargo-only aircraft. For materials that are authorized to exceed 220 L (58 gallons) or 200 kg (441 pounds) in accordance with columns (9A) and (9B) of the § 172.101 Hazardous Materials Table, there is no limitation on the maximum authorized net capacity of each inner packaging.

(1) *Excepted quantities.* For authorized materials and inner and outer package quantity limits for combination packages of excepted quantities intended for transportation by aircraft, *see* § 173.4a of this part.

* * * * *

(3) * * *

TABLE 1 TO PARAGRAPH (f)—MAXIMUM NET CAPACITY OF INNER PACKAGING FOR TRANSPORTATION ON PASSENGER-CARRYING AIRCRAFT

Maximum net quantity per package from Column 9a of the § 172.101 table	Maximum authorized net capacity of each inner packaging	
	Glass, earthenware or fiber inner packagings	Metal or plastic inner packagings
Liquids:		
Not greater than 0.5 L	0.5 L	0.5 L.
Greater than 0.5 L, not greater than 1 L	0.5 L	1 L.
Greater than 1 L, not greater than 5 L	1 L	5 L.
Greater than 5 L, not greater than 60 L	2.5 L	10 L.
Greater than 60 L, not greater than 220 L	5 L	25 L.
Class 9: UN1941, UN1990, UN2315, UN3082, UN3151, UN3334	10 L	Plastic: 30 L; Metal: 40 L.
Solids:		
Not greater than 5 kg	0.5 kg	1 kg.
Greater than 5 kg. not greater than 25 kg	1 kg	2.5 kg.
Greater than 25 kg, not greater than 200 kg	5 kg	10 kg.
Class 9: UN1841, UN1931, UN2071, UN2216, UN2590, UN2969, UN3077, UN3152, UN3335, UN3432.	Glass or earthenware: 10 kg; Fiber: 50 kg.	50 kg.

TABLE 2 TO PARAGRAPH (f)—MAXIMUM NET CAPACITY OF INNER PACKAGING FOR TRANSPORTATION ON CARGO AIRCRAFT

Maximum net quantity per package from Column 9b of the § 172.101 table	Maximum authorized net capacity of each inner packaging	
	Glass, earthenware or fiber inner packagings	Metal or plastic inner packagings
Liquids:		
Not greater than 2.5L	1 L	1 L.
Greater than 2.5L, not greater than 30L	2.5 L	2.5 L.
Greater than 30L, not greater than 60L	5 L	10 L.
Greater than 60L, not greater than 220L	5 L	25 L.
Class 9: UN1941, UN1990, UN2315, UN3082, UN3151, UN3334	10 L	Plastic: 30 L; Metal: 40 L.
Solids:		
Not greater than 15 kg	1 kg	1 kg.
Greater than 15 kg. not greater than 50 kg	2.5 kg	5 kg.
Greater than 50 kg, not greater than 200 kg	5 kg	10 kg.
Class 9: UN1841, UN1931, UN2071, UN2216, UN2590, UN2969, UN3077, UN3152, UN3335, UN3432.	Glass or earthenware: 10 kg; Fiber: 50 kg.	50 kg.

Table 3 to Paragraph (f)—Maximum Net Quantity of Each Inner and Outer Packaging for Materials Authorized for Transportation as Limited Quantity by Aircraft

* * * * *

■ 19. In § 173.59, revise the description for ''Detonators'' and add a description for ''Detonators, electronic programmable for blasting'' in alphabetical order to read as follows:

§ 173.59 Description of terms for explosives.

* * * * *

Detonators. Articles consisting of a small metal or plastic tube containing explosives such as lead azide, PETN, or combinations of explosives. They are designed to start a detonation train. They may be constructed to detonate instantaneously or may contain a delay element. They may contain no more than 10 g of total explosives weight, excluding ignition and delay charges, per unit. The term includes: detonators for ammunition; detonators for blasting (electric, electronic, and non-electric); and detonating relays without flexible detonating cord.

Detonators, electronic programmable for blasting. Detonators using electronic components, such as an integrated circuit and/or micro processing technology to provide communications, energy control and storage capability, timing delay information, and validated commands to send a firing signal to the initiating charge.

* * * * *

■ 20. In § 173.115, revise paragraph (k) to read as follows:

§ 173.115 Class 2, Divisions 2.1, 2.2, and 2.3—Definitions.

* * * * *

(k) For Division 2.2 gases, the oxidizing ability shall be determined by tests or by calculation in accordance with ISO 10156:2017(E) (IBR, *see* § 171.7 of this subchapter).

* * * * *

■ 21. In § 173.134, revise paragraphs (a)(1) and (5) to read as follows:

§ 173.134 Class 6, Division 6.2—Definitions and exceptions.

(a) * * *

(1) *Division 6.2 (Infectious substance)* means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, parasites, and fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals. An infectious substance must be assigned the identification number UN2814, UN2900, UN3291, UN3373, or UN3549 as appropriate, and must be assigned to one of the following categories:

(i) *Category A:* An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. A Category A infectious substance must be assigned to identification number UN2814,

UN2900, or UN3549, as appropriate. Assignment to UN2814, UN2900, or UN3549 must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.

(ii) *Category B:* An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes. A Category B infectious substance must be described as ''Biological substance, Category B'' and assigned identification number UN3373. This does not include regulated medical waste, which must be assigned identification number UN3291.

* * * * *

(5) *Regulated medical waste or clinical waste or (bio) medical waste* means a waste or reusable material derived from the medical treatment of an animal or human, which includes diagnosis and immunization, or from biomedical research, which includes the production and testing of biological products. Regulated medical waste or clinical waste or (bio) medical waste containing a Category A infectious substance must be classed as an infectious substance, and assigned to UN2814, UN2900, or UN3549, as appropriate.

* * * * *

■ 22. In § 173.137, revise the introductory text to read as follows:

§ 173.137 Class 8—Assignment of packing group.

The packing group of a Class 8 material is indicated in Column 5 of the § 172.101 Table. When the § 172.101 Table provides more than one packing group for a Class 8 material, the packing group must be determined using data obtained from tests conducted in accordance with the OECD Guidelines for the Testing of Chemicals, Test No. 435, ''*In Vitro* Membrane Barrier Test Method for Skin Corrosion'' (IBR, *see* § 171.7 of this subchapter) or Test No. 404, ''Acute Dermal Irritation/Corrosion'' (IBR, *see* § 171.7 of this subchapter). A material that is determined not to be corrosive in accordance with OECD Guideline for the Testing of Chemicals, Test No. 430, ''*In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)'' (IBR, *see* § 171.7 of this subchapter) or Test No. 431, ''*In Vitro* Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method'' (IBR, *see* § 171.7 of this subchapter) may be considered not to be corrosive to human skin for the purposes of this subchapter without further testing. However, a material determined to be corrosive in accordance with Test No. 430 must be further tested using Test No. 435 or Test No. 404. If the in vitro test results indicate that the substance or mixture is corrosive, but the test method does not clearly distinguish between assignment of packing groups II and III, the material may be considered to be in packing group II without further testing. The packing group assignment using data obtained from tests conducted in accordance with OECD Guideline Test No. 404 or Test No. 435 must be as follows:

* * * * *

■ 23. In § 173.172, revise paragraphs (a) and (b) to read as follows:

§ 173.172 Aircraft hydraulic power unit fuel tank.

* * * * *

(a) The unit must consist of an aluminum pressure vessel made from tubing and having welded heads. Primary containment of the fuel within this vessel must consist of a welded aluminum bladder having a maximum internal volume of 46 L (12 gallons). The outer vessel must have a minimum design gauge pressure of 1,275 kPa (185 psig) and a minimum burst gauge pressure of 2,755 kPa (400 psig). Each vessel must be leak-checked during manufacture and before shipment and must be found leakproof. The complete inner unit must be securely packed in non-combustible cushioning material, such as vermiculite, in a strong outer tightly closed metal packaging which will adequately protect all fittings. Maximum quantity of fuel per primary containment and package is 42 L (11 gallons); or

(b) The unit must consist of an aluminum pressure vessel. Primary containment of the fuel within this vessel must consist of a welded hermetically sealed fuel compartment with an elastomeric bladder having a maximum internal volume of 46 L (12 gallons). The pressure vessel must have a minimum design gauge pressure of 5,170 kPa (750 psig). Each vessel must be leak-checked during manufacture and before shipment and must be found leakproof, and must be securely packed in non-combustible cushioning material, such as vermiculite, in a strong outer tightly closed metal packaging which will adequately protect all fittings. Maximum quantity of fuel per primary containment and package is 42 L (11 gallons).

■ 24. In § 173.181, revise paragraph (b) to read as follows:

§ 173.181 Pyrophoric materials (liquids).

* * * * *

(b) Steel boxes (4A), aluminum boxes (4B), metal boxes, other than steel or aluminum (4N), wooden boxes (4C1, 4C2, 4D, or 4F) or fiberboard boxes (4G); steel drums (1A1 or 1A2), aluminum drums (1B1 or 1B2), metal drums, other than steel or aluminum (1N1 or 1N2), plywood drums (1D), or fiber drums (1G); or steel jerricans (3A1 or 3A2) or aluminum jerricans (3B1 or 3B2) enclosing not more than four strong, tight metal cans with inner receptacles of glass or metal, not over 1 L (0.3 gallon) capacity each, having positive screwcap closures adequately gasketed or alternative closures physically held in place by a means capable of preventing back-off or loosening of the closure due to conditions normally incident to transportation (*e.g.,* impact, vibration, etc.). Inner packagings must be cushioned on all sides with dry, absorbent, incombustible material in a quantity sufficient to absorb the entire contents.

* * * * *

■ 25. In § 173.185, revise paragraphs (c)(3)(i) introductory text and (c)(3)(i)(A) to read as follows:

§ 173.185 Lithium cell and batteries.

* * * * *

(c) * * *

(3) * * *

(i) The mark must indicate the UN number: ''UN3090'' for lithium metal cells or batteries; or ''UN3480'' for lithium ion cells or batteries. Where the lithium cells or batteries are contained in, or packed with, equipment, the UN number ''UN3091'' or ''UN3481,'' as appropriate, must be indicated. Where a package contains lithium cells or batteries assigned to different UN numbers, all applicable UN numbers must be indicated on one or more marks. The package must be of such size that there is adequate space to affix the mark on one side without the mark being folded.

Figure 1 to paragraph (c)(3)(i) introductory text

(A) The mark must be in the form of a rectangle or a square with hatched edging. The mark must be not less than 100 mm (3.9 inches) wide by 100 mm (3.9 inches) high and the minimum width of the hatching must be 5 mm (0.2 inches), except marks of 100 mm (3.9 inches) wide by 70 mm (2.8 inches) high may be used on a package containing lithium batteries when the package is too small for the larger mark;

* * * * *

■ 26. In § 173.187, revise paragraphs (b), (c), (e), and (f) to read as follows:

§ 173.187 Pyrophoric solids, metals or alloys, n.o.s.

* * * * *

(b) In wooden boxes (4C1, 4C2, 4D, or 4F) with inner metal receptacles that have threaded closures or alternate closures physically held in place by a means capable of preventing back-off or loosening of the closure due to conditions normally incident to transportation (*e.g.,* impact, vibration, etc.). Each inner metal receptacle must not contain more than 15 kg (33 pounds).

(c) In fiberboard boxes (4G) with inner metal receptacles that have threaded closures or alternate closures physically held in place by a means capable of preventing back-off or loosening of the closure due to conditions normally incident to transportation (*e.g.,* impact, vibration, etc.). Each inner metal receptacle must not contain more than 7.5 kg (17 pounds).

* * * * *

(e) In plywood drums (1D) with inner metal receptacles that have threaded closures or alternate closures physically held in place by a means capable of preventing back-off or loosening of the closure due to conditions normally incident to transportation (*e.g.,* impact, vibration, etc.). Each inner metal receptacle must not contain more than 15 kg (33 pounds).

(f) In fiberboard drums (1G) with inner metal receptacles that have threaded closures or alternate closures physically held in place by a means capable of preventing back-off or loosening of the closure due to conditions normally incident to transportation (*e.g.,* impact, vibration, etc.) Each inner metal receptacle must not contain more than 15 kg (33 pounds).

* * * * *

■ 27. In § 173.199, revise the paragraph (a)(5) introductory text preceding the image of the UN3373 mark to read as follows:

§ 173.199 Category B infectious substances.

(a) * * *

(5) The following square-on-point mark must be displayed on the outer packaging on a background of contrasting color. The width of the line forming the border must be at least 2 mm (0.08 inches) and the letters and numbers must be at least 6 mm (0.24 inches) high. The size of the mark must be such that no side of the diamond is less than 50 mm (1.97 inches) in length as measured from the outside of the lines forming the border. For transportation by aircraft, the entire mark must appear on one side of the package. The proper shipping name ''Biological substances, Category B'' must be marked on the outer packaging adjacent to the diamond-shaped mark in letters that are at least 6 mm (0.24 inches) high.

* * * * *

■ 28. Revise § 173.218 to read as follows:

§ 173.218 Fish meal or fish scrap.

(a) *Transportation by vessel.* (1) Except as provided in Column (7) of the HMT in § 172.101 of this subchapter, fish meal or fish scrap, containing at least 6%, but not more than 12% water, is authorized for transportation in packagings as follows:

(i) Burlap (jute) bag;
(ii) Multi-wall paper bag;
(iii) Polyethylene-lined burlap or paper bag;
(iv) Cargo tank;
(v) Portable tank;
(vi) Rail car; or
(vii) Freight container.

(2) The fish meal or fish scrap must contain at least 50 ppm (mg/kg) of ethoxyquin, 100 ppm (mg/kg) of butylated hydroxytoluene (BHT), or 250

ppm (mg/kg) of tocopherol-based antioxidant at the time of shipment. Stabilization of fish meal or fish scrap must occur at the time of production and the application must be within twelve months prior to shipment.

(b) *Transportation by air.* (1) Except as provided in Column (7) of the HMT in § 172.101 of this subchapter, fish meal or fish scrap, containing at least 6%, but not more than 12% water, is authorized for transportation in packagings as follows:

(i) The following combination packagings are authorized:

(A) *Outer packagings:* Steel drum: 1A1 or 1A2; Aluminum drum: 1B1 or 1B2; Metal drum other than steel or aluminum: 1N1 or 1N2; Fiber drum: 1G; Plastic drum: 1H1 or 1H2; Steel jerrican: 3A1 or 3A2; Plastic jerrican: 3H1 or 3H2; Aluminum jerrican: 3B1 or 3B2; Steel box: 4A; Aluminum box: 4B; Natural wood box: 4C1 or 4C2; Plywood box: 4D; Reconstituted wood box: 4F; Fiberboard box: 4G; Solid plastic box: 4H2; or Metal box other than steel or aluminum: 4N.

(B) *Inner packagings:* Glass, Fiber, Metal, or Plastic.

(ii) The following single packagings are authorized:

(A) Steel drum: 1A1 or 1A2; Aluminum drum: 1B1 or 1B2; Plywood drum with liner: 1D; Plastic drum: 1H1 or 1H2; Fiber drum with liner: 1G; Metal drum other than steel or aluminum: 1N1 or 1N2; Steel jerrican: 3A1 or 3A2; Plastic jerrican: 3H1 or 3H2; Aluminum jerrican: 3B1 or 3B2; Steel box: 4A; Aluminum box: 4B; Metal box other than steel or aluminum: 4N; Natural wood box with liner: 4C2; Plywood box with liner: 4D; Reconstituted wood box with liner: 4F; Fiberboard box with liner: 4G; Solid plastic box: 4H2; Bag, woven plastic: 5H3; Bag, plastic film: 5H4; Bag, textile: 5L3; Bag, paper, multiwall, water resistant: 5M2; Plastic receptacle in steel, aluminum, plywood, fiber or plastic drum: 6HA1, 6HB1, 6HD1, 6HG1 or 6HH1; Plastic receptacle in steel, aluminum, wood, plywood or fiberboard box: 6HA2, 6HB2, 6HC, 6HD2, 6HG2 or 6HH2; or Cylinders, as prescribed for any compressed gas, except for Specification 8 and 3HT.

(B) [Reserved]

(2) The fish meal or fish scrap must contain at least 50 ppm (mg/kg) of ethoxyquin, 100 ppm (mg/kg) of butylated hydroxytoluene (BHT), or 250 ppm (mg/kg) of tocopherol-based antioxidant at the time of shipment. Stabilization of fish meal or fish scrap must occur at the time of production and the application must be within twelve months prior to shipment.

■ 29. In § 173.221, revise paragraph (a) to read as follows:

§ 173.221 Polymeric beads, expandable and Plastic molding compound.

(a) For non-bulk shipments of Polymeric beads (or granules), expandable *evolving flammable vapor* and Plastic molding compound *in dough, sheet, or extruded rope form, evolving flammable vapor* the following packagings are authorized:

(1) *Single packagings.* Metal box (4A, 4B, or 4N); Wooden box (4C1 or 4C2); Plywood box (4D); Fiberboard box (4G); Reconstituted wood box (4F); Plastic box (4H1 or 4H2); Plywood drums: (1D) or Fiber drums (1G) with sealed inner plastic liners; in vapor tight metal or plastic drums (1A1, 1A2, 1B1, 1B2, 1N1, 1N2, 1H1 or 1H2); or in vapor tight metal or plastic jerricans (3A1, 3A2, 3B1, 3B2, 3H1, or 3H2).

(2) *Combination packagings*—(i) *Outer packagings:* Steel drum: 1A1 or 1A2; Aluminum drum: 1B1 or 1B2; Plywood drum: 1D; Fiber drum: 1G; Plastic drum: 1H1 or 1H2; Metal drum other than steel or aluminum: 1N1 or 1N2; Steel jerrican: 3A1 or 3A2; Plastic jerrican: 3H1 or 3H2; Aluminum jerrican: 3B1 or 3B2; Steel box: 4A; Aluminum box: 4B; Natural wood box: 4C1 or 4C2; Plywood box: 4D; Reconstituted wood box: 4F; Fiberboard box: 4G; Plastic box: 4H1 or 4H2; or Metal box other than steel or aluminum: 4N.

(ii) *Inner packagings.* Glass receptacles, Plastic receptacles, Metal receptacles, Paper receptacles, or Fiber receptacles.

(3) *Non-specification packagings.* Non-specification packagings when transported in dedicated vehicles or freight containers. The packagings need not conform to the requirements for package testing in part 178 of this subchapter but must be capable of containing any evolving gases from the contents during normal conditions of transportation.

* * * * *

■ 30. Revise § 173.222 to read as follows:

§ 173.222 Dangerous goods in articles, machinery, or apparatus.

Hazardous materials in articles, machinery, or apparatus are excepted from the specification packaging requirements of this subchapter when packaged according to this section. Hazardous materials in articles, machinery, or apparatus must be packaged in strong outer packagings, unless the receptacles containing the hazardous materials are afforded adequate protection by the construction of the article, machinery, or apparatus. Each package must conform to the packaging requirements of subpart B of this part, except for the requirements in §§ 173.24(a)(1) and 173.27(e), and the following requirements:

(a) If the article, machinery, or apparatus contains more than one hazardous material, the materials must not be capable of reacting dangerously together.

(b) The nature of the containment must be as follows—

(1) Damage to the receptacles containing the hazardous materials during transport is unlikely. However, in the event of damage to the receptacles containing the hazardous materials, no leakage of the hazardous materials from the article, machinery, or apparatus is possible. A leakproof liner may be used to satisfy this requirement.

(2) Receptacles containing hazardous materials must be secured and cushioned so as to prevent their breakage or leakage and so as to control their shifting within the article, machinery, or apparatus during normal conditions of transportation. Cushioning material must not react dangerously with the content of the receptacles. Any leakage of the contents must not substantially impair the protective properties of the cushioning material.

(3) Receptacles for gases, their contents and filling densities must conform to the applicable requirements of this subchapter, unless otherwise approved by the Associate Administrator.

(c)(1) Except for transportation by aircraft, the total net quantity of hazardous materials contained in one item of an article, machinery, or apparatus must not exceed the following:

(i) In the case of solids or liquids, the limited quantity amount specified in the corresponding section referenced in Column (8A) of the § 172.101 Table;

(ii) 0.5 kg (1.1 pounds) in the case of Division 2.2 gases.

(iii) When an article, machinery, or apparatus contains multiple hazardous materials, the quantity of each hazardous material must not exceed the quantity specified in the corresponding section referenced in Column (8A) of the § 172.101 Table, or for gases, paragraph (c)(1)(ii) of this section.

(2) For transportation by aircraft, the total net quantity of hazardous materials contained in one item of an article, machinery, or apparatus must not exceed the following:

(i) 1 kg (2.2 pounds) in the case of solids;

(ii) 0.5 L (0.1 gallons) in the case of liquids;

(iii) 0.5 kg (1.1 pounds) in the case of Division 2.2 gases. Division 2.2 gases with subsidiary risks and refrigerated liquefied gases are not authorized;

(iv) A total quantity of not more than the aggregate of that permitted in paragraphs (c)(2)(i) through (iii) of this section, for each category of material in the package, when a package contains hazardous materials in two or more of the categories in paragraphs (c)(2)(i) through (iii) of this section; and

(d) Except for transportation by aircraft, when a package contains hazardous materials in two or more of the categories listed in paragraph (c)(1) of this section the total quantity required by § 172.202(c) of this subchapter to be entered on the shipping paper must be either the aggregate quantity, or the estimated quantity, of all hazardous materials, expressed as net mass.

■ 31. In § 173.225:

■ a. In paragraph (c), revise the heading to the Organic Peroxide Table and revise the entry ''Di-(4-tert-butylcyclohexyl) peroxydicarbonate [as a paste]''; and

■ b. In paragraph (e), revise the heading to the Organic Peroxide IBC Table, and in the UN3119 ORGANIC PEROXIDE, TYPE F, LIQUID, TEMPERATURE CONTROLLED portion, add entries for ''tert-Amyl peroxypivalate, not more than 42% as a stable dispersion in water'' and ''tert-Butyl peroxypivalate, not more than 42% in a diluent type A'' in alphabetical order.

The revisions and additions read as follows:

§ 173.225 Packaging requirements and other provisions for organic peroxides.

* * * * *

(c) * * *

TABLE 1 TO PARAGRAPH (c)—ORGANIC PEROXIDE TABLE

Technical name	ID No.	Concentration (mass %)	Diluent (mass %)			Water (mass %)	Packing method	Temperature (°C)		Notes
			A	B	I			Control	Emergency	
(1)	(2)	(3)	(4a)	(4b)	(4c)	(5)	(6)	(7a)	(7b)	(8)
* *		*	*		*		*		*	
Di-(4-tert-butylcyclohexyl)peroxydicarbonate [as a paste]	UN3118	≤42	.....	.....	.....	.....	OP8	35	40	
* *		*	*		*		*		*	

* * * * *

(e) * * *

TABLE 3 TO PARAGRAPH (e)—ORGANIC PEROXIDE IBC TABLE

UN No.	Organic peroxide	Type of IBC	Maximum quantity (liters)	Control temperature	Emergency temperature
*	* * *	*		*	*
3119	ORGANIC PEROXIDE, TYPE F, LIQUID, TEMPERATURE CONTROLLED.				
*	* * *	*		*	*
	tert-Amyl peroxypivalate, not more than 42% as a stable dispersion in water.	31HA1	1,000	0 °C	+10 °C
	tert-Butyl peroxypivalate, not more than 42% in a diluent type A	31HA1	1,000	10 °C	15 °C
		31A	1,250	10 °C	15 °C
*	* * *	*		*	*

* * * * *

■ 32. In § 173.301b, revise paragraphs (a)(2) and (c) to read as follows:

§ 173.301b Additional general requirements for shipment of UN pressure receptacles.

(a) * * *

(2) The gases or gas mixtures must be compatible with the UN pressure receptacle and valve materials as prescribed for metallic materials in ISO 11114–1:2012(E) and ISO 11114–1:2012/Amd 1:2017(E) (IBR, *see* § 171.7 of this subchapter) and for non-metallic materials in ISO 11114–2:2013(E) (IBR, *see* § 171.7 of this subchapter).

* * * * *

(c) *Pressure receptacle valve requirements.* (1) When the use of a valve is prescribed, the valve must conform to the requirements in ISO 10297:2014(E) and ISO 10297:2014/Amd 1:2017 (IBR, *see* § 171.7 of this subchapter). Quick release cylinder valves for specification and type testing must conform to the requirements in ISO 17871:2015(E) (IBR, *see* § 171.7 of this subchapter). Until December 31, 2022, the manufacture of a valve conforming to the requirements in ISO 10297:2014(E) is authorized. Until December 31, 2020, the manufacture of a valve conforming to the requirements in ISO 10297:2006(E) (IBR, *see* § 171.7 of this subchapter) was authorized. Until December 31, 2008, the manufacture of a valve conforming to the requirements in ISO 10297:1999(E) (IBR, *see* § 171.7 of this subchapter) was authorized.

(2) A UN pressure receptacle must have its valves protected from damage that could cause inadvertent release of the contents of the UN pressure receptacle by one of the following methods:

(i) By constructing the pressure receptacle so that the valves are recessed inside the neck of the UN pressure receptacle and protected by a threaded plug or cap;

(ii) By equipping the UN pressure receptacle with a valve cap conforming

to the requirements in ISO 11117:2008(E) and Technical Corrigendum 1 (IBR, *see* § 171.7 of this subchapter). Until December 31, 2014, the manufacture of a valve cap conforming to the requirements in ISO 11117:1998(E) (IBR, *see* § 171.7 of this subchapter) was authorized. The cap must have vent-holes of sufficient cross-sectional area to evacuate the gas if leakage occurs at the valve;

(iii) By protecting the valves by shrouds or guards conforming to the requirements in ISO 11117:2008(E) and Technical Corrigendum 1 (IBR; *see* § 171.7 of this subchapter). Until December 31, 2014, the manufacture of a shroud or guard conforming to the requirements in ISO 11117:1998(E) (IBR, *see* § 171.7 of this subchapter) was authorized. For metal hydride storage systems, by protecting the valves in accordance with the requirements in ISO 16111:2008(E) (IBR; *see* § 171.7 of this subchapter).

(iv) By using valves designed and constructed with sufficient inherent strength to withstand damage in accordance with Annex B of ISO 10297:2014(E)/Amd. 1: 2017;

(v) By enclosing the UN pressure receptacles in frames (*e.g.,* bundles of cylinders);

(vi) By packing the UN pressure receptacles in a strong outer package, such as a box or crate, capable of meeting the drop test specified in § 178.603 of this subchapter at the Packing Group I performance level; or

(vii) By using valves designed and constructed in accordance with Annex A of ISO 17879:2017(E) (IBR, *see* § 171.7 of this subchapter) for UN pressure receptacles with self-closing valves with inherent protection (except those in acetylene service).

* * * * *

■ 33. In § 173.304b, revise paragraph (b)(2) to read as follows:

§ 173.304b Additional requirements for shipment of liquefied compressed gases in UN pressure receptacles.

* * * * *

(b) * * *

(2) For low pressure liquefied gases, the maximum mass in kilograms of contents per liter of water capacity must be less than or equal to 95 percent of the liquid phase at 50 °C. In addition, the UN pressure receptacle may not be liquid full at 60 °C. The test pressure of the pressure receptacle must be equal to or greater than the vapor pressure of the liquid at 65 °C.

* * * * *

■ 34. In § 173.306, revise paragraphs (f)(2)(i) and (f)(3)(iv) and add paragraph (n) to read as follows:

§ 173.306 Limited quantities of compressed gases.

* * * * *

(f) * * *

(2) * * *

(i) Each accumulator must be shipped as an inside packaging. Robust accumulators may be transported unpackaged, in crates, or in appropriate overpacks, when the hazardous materials are afforded equivalent protection by the article in which they are contained;

* * * * *

(3) * * *

(iv) Accumulators must be packaged in strong outer packaging. Robust accumulators may be transported unpackaged, in crates, or in appropriate overpacks, when the hazardous materials are afforded equivalent protection by the article in which they are contained.

* * * * *

(n) *Receptacles, small, containing gas or gas cartridges for recycling or disposal.* Receptacles, small, containing gas *or* gas cartridges not exceeding 1.0 L (0.3 gallons) capacity may be offered for transportation for the purposes of recycling or disposal. Receptacles, small, containing gas *or* gas cartridges are not required to be protected against shifting and inadvertent discharge if measures to prevent dangerous build-up of pressure and dangerous atmospheres are addressed and are excepted from the specification packaging requirements of this subchapter when packaged and offered in accordance with this paragraph (n).

(1) Receptacles, small, containing gas *or* gas cartridges for recycling or disposal, other than those that are leaking or severely deformed, must be packaged as follows:

(i) The receptacles, small, containing gas *or* gas cartridges must be packaged in a strong outer packaging. The strong outer packaging and its contents must not exceed a gross weight of 55 kg (121 pounds) for fiberboard packagings or 125 kg (275 pounds) for other packagings; and

(ii) Packagings must be adequately ventilated to prevent the creation of dangerous atmospheres and build-up of pressure.

(2) Rigid large packagings are authorized conforming to the packing group II performance level made of:

(i) Steel (50A); Aluminum (50B); Metal other than steel or aluminum (50N); Rigid plastics (50H); Natural wood (50C); Plywood (50D); Reconstituted wood (50F); Rigid fiberboard (50G).

(ii) Large packagings must be designed and constructed to prevent dangerous shifting and inadvertent discharge during normal conditions of transport;

(iii) Large packagings must be adequately ventilated to prevent the creation of dangerous atmospheres and the build-up of pressure; and

(iv) Leaking or severely deformed containers must be transported in salvage cylinders or salvage packagings provided adequate measures are taken to prevent a dangerous build-up of pressure.

(3) Receptacles, small, containing gas *or* gas cartridges for recycling or disposal must not be transported in closed freight containers.

(4) Receptacles, small, containing gas *or* gas cartridges for recycling or disposal that were filled with Division 2.2 gases and have been pierced are not subject to the requirements of this subchapter.

■ 35. In § 173.335, revise paragraph (d) to read as follows:

§ 173.335 Chemical under pressure n.o.s.

* * * * *

(d) *Periodic inspection.* (1) Except as specified in (d)(2) of this section, the maximum requalification test period for cylinders transporting chemical under pressure n.o.s. is 5 years.

(2) For cylinders with maximum capacity of 450 L or less and filled with materials used as fire extinguishing agents, the maximum requalification test period is 10 years.

PART 175—CARRIAGE BY AIRCRAFT

■ 36. The authority citation for part 175 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81 and 1.97.

■ 37. In § 175.8, add paragraph (b)(5) to read as follows:

§ 175.8 Exceptions for operator equipment and items of replacement.

* * * * *

(b) * * *

(5) Alcohol-based hand sanitizers and alcohol-based cleaning products that are accessible to crewmembers in the passenger cabin during the flight or series of flights for the purposes of passenger and crew hygiene. Conditions for the carriage and use must be described in an operations manual and/or other appropriate manuals.

■ 38. In § 175.9, revise paragraph (b)(5)(ii) to read as follows:

§ 175.9 Special aircraft operations.

* * * * *

(b) * * *

(5) * * *

(ii) Each type of battery used is either nonspillable, lithium metal, or lithium

ion. Lithium metal or lithium ion batteries must meet the provisions of § 173.185(a) of this subchapter. Spare batteries—of any type—must be individually protected to prevent short circuits when not in use;

* * * * *

■ 39. In § 175.10, revise paragraphs (a)(1) and (11) to read as follows:

§ 175.10 Exceptions for passengers, crewmembers, and air operators.

* * * * *

(a) * * *

(1)(i) Non-radioactive medicinal and toilet articles for personal use (including aerosols) carried in carry-on and checked baggage. Release devices on aerosols must be protected by a cap or other suitable means to prevent inadvertent release;

(ii) Other aerosols in Division 2.2 (nonflammable gas) with no subsidiary risk carried in carry-on or checked baggage. Release devices on aerosols must be protected by a cap or other suitable means to prevent inadvertent release;

(iii) The aggregate quantity of these hazardous materials carried by each person may not exceed 2 kg (70 ounces) by mass or 2 L (68 fluid ounces) by volume and the capacity of each container may not exceed 0.5 kg (18 ounces) by mass or 500 ml (17 fluid ounces) by volume; and

(iv) The release of gas must not cause extreme annoyance or discomfort to crew members so as to prevent the correct performance of assigned duties.

* * * * *

(11) No more than two self-inflating personal safety devices, intended to be worn by a person such as a life jacket or vest, fitted with no more than two small gas cartridges per device (containing no hazardous material other than a Division 2.2 gas) for inflation purposes plus no more than two spare cartridges per device. The personal safety device(s) and spare cartridges may be carried in carry-on or checked baggage, with the approval of the aircraft operator, and must be packed in such a manner that they cannot be accidently activated.

* * * * *

■ 40. In § 175.75, revise paragraph (b) and Notes 1 and 2 to the Quantity and Loading Table in paragraph (f) to read as follows:

§ 175.75 Quantity limitations and cargo location.

* * * * *

(b) *Hazardous materials stowage.* (1) Except as otherwise provided in this subchapter, no person may carry a hazardous material in the cabin of a passenger-carrying aircraft or on the flight deck of any aircraft, and the hazardous material must be located in a place that is inaccessible to persons other than crew members.

(2) Hazardous materials may be carried in a main deck cargo compartment of a passenger aircraft provided that the compartment is inaccessible to passengers and that it meets all certification requirements for: a Class B aircraft cargo compartment in 14 CFR 25.857(b); or a Class C aircraft cargo compartment in 14 CFR 25.857(c).

(3) A package bearing a ''KEEP AWAY FROM HEAT'' handling marking must be protected from direct sunshine and stored in a cool and ventilated place, away from sources of heat.

(4) Except as provided in paragraph (f) of this section, a package containing a hazardous material acceptable for cargo-only aircraft must be loaded in an accessible manner.

* * * * *

(f) * * *

Note 1 to § 175.75(f): The following materials are not subject to this loading restriction—

a. Class 3, PG III (unless the substance is also labeled CORROSIVE).

b. Division 6.1 (unless the substance is also labeled for any hazard class or division except FLAMMABLE LIQUID).

c. Division 6.2.

d. Class 7 (unless the hazardous material meets the definition of another hazard class).

e. Class 9, Limited Quantity, or Excepted Quantity material.

f. Articles of Identification Numbers UN0012, UN0014, or UN0055 also meeting the requirements of § 173.63(b).

g. Articles of Identification Numbers UN3528 or UN3529.

Note 2 to § 175.75(f): Aboard cargo-only aircraft, packages required to be loaded in a position that is considered to be accessible include those loaded in a Class C cargo compartment.

PART 176—CARRIAGE BY VESSEL

■ 41. The authority citation for part 176 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 42. In § 176.84:

■ a. In the paragraph (b) table, revise code 4 and add codes 155, 156, and 157 in numerical order; and

■ b. In the paragraph (c)(2) table, revise provisions 19E and 22E.

The revisions read as follows:

§ 176.84 Other requirements for stowage, cargo handling, and segregation for cargo vessels and passenger vessels.

* * * * *

(b) * * *

Code	Provisions
*	* * * * * * *
4	Shall not be stowed together with combustible material in the same cargo transport unit.
*	* * * * * * *
155	Avoid handling the package or keep handling to a minimum. Inform the appropriate public health authority or veterinary authority where persons or animals may have been exposed.
156	For lithium batteries transported in accordance with § 173.185(f) or for purposes of disposal or recycling, stowage category C applies.
157	For aerosols and gas receptacles transported for purposes of recycling or disposal, stowage category C applies, and stowage must be clear of living quarters.
*	* * * * * * *

* * * * *

(c) * * *

(2) * * *

Notes	Provisions
* * * * * * *	
19E	"Separated from" explosives containing chlorates or perchlorates.
* * * * * * *	
22E	"Separated from" ammonium compounds and explosives containing ammonium compounds or salts.
* * * * * * *	

* * * * *

PART 178—SPECIFICATIONS FOR PACKAGINGS

■ 43. The authority citation for part 178 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 44. In § 178.3, revise paragraph (a)(4) to read as follows:

§ 178.3 Marking of packagings.

(a) * * *

(4) Unless otherwise specified, letters and numerals must be at least 12.0 mm (0.47 inches) in height except for packagings of less than or equal to 30 L (7.9 gallons) capacity for liquids or 30 kg (66 pounds) maximum net mass for solids the height must be at least 6.0 mm (0.2 inches). For packagings having a capacity of 5 L (1.3 gallons) or less or of 5 kg (11 pounds) maximum net mass, letters and numerals must be of an appropriate size.

* * * * *

■ 45. In § 178.71, revise paragraph (d)(2), add paragraph (l)(1)(iv), and revise paragraph (o)(1) to read as follows:

§ 178.71 Specifications for UN pressure receptacles.

* * * * *

(d) * * *

(2) Service equipment must be configured, or designed, to prevent damage that could result in the release of the pressure receptacle contents during normal conditions of handling and transport. Manifold piping leading to shut-off valves must be sufficiently flexible to protect the valves and the piping from shearing or releasing the pressure receptacle contents. The filling and discharge valves and any protective caps must be secured against unintended opening. The valves must conform to ISO 10297:2014(E) and ISO 10297:2014/Amd 1:2017(E) (IBR, *see* § 171.7 of this subchapter), or for non-refillable pressure receptacles valves manufactured until December 31, 2020, ISO 13340:2001(E), and be protected as specified in § 173.301b(f) of this subchapter. Until December 31, 2022, the manufacture of a valve conforming to the requirements of ISO 10297:2014(E) is authorized. Until December 31, 2020, the manufacture of a valve conforming to the requirements in ISO 10297:2006(E) (IBR, *see* § 171.7 of this subchapter) was authorized. Until December 31, 2008, the manufacture of a valve conforming to the requirements in ISO 10297:1999(E) (IBR, *see* § 171.7 of this subchapter) was authorized. Additionally, valves must be initially inspected and tested in accordance with ISO 14246:2014(E) and ISO 14246:2014/Amd 1:2017(E), (IBR, *see* § 171.7 of this subchapter). For self-closing valves with inherent protection, the requirements of ISO 17879:2017(E) (IBR, *see* § 171.7 of this subchapter) shall be met until further notice.

* * * * *

(l) * * *

(1) * * *

(iv) ISO 11119–4:2016(E) (IBR, *see* § 171.7 of this subchapter).

* * * * *

(o) * * *

(1) ISO 11114–1:2012(E) and 11114–1:2012/Amd 1:2017(E) (IBR, *see* § 171.7 of this subchapter).

* * * * *

■ 46. In § 178.75, revise paragraph (d)(3) introductory text and add paragraphs (d)(3)(vi) through (ix) to read as follows:

§ 178.75 Specifications for MEGCs.

* * * * *

(d) * * *

(3) Each pressure receptacle of a MEGC must be of the same design type, seamless steel, or composite, and constructed and tested according to one of the following ISO standards, as appropriate:

* * * * *

(vi) ISO 11119–1:2012(E), Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 1: Hoop wrapped fibre reinforced composite gas cylinders and tubes up to 450 l (IBR, *see* § 171.7 of this subchapter).

(vii) ISO 11119–2:2012(E) and ISO 11119–2:2012/Amd.1:2014(E), Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 2: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 l with load-sharing metal liners (both IBR, *see* § 171.7 of this subchapter).

(viii) ISO 11119–3:2013(E) Gas cylinders—Refillable composite gas cylinders and tubes—Design, construction and testing—Part 3: Fully wrapped fibre reinforced composite gas cylinders and tubes up to 450 l with non-load-sharing metallic or non-metallic liners (IBR, *see* § 171.7 of this subchapter).

(ix) ISO 11119–4:2016(E) Gas cylinders—Refillable composite gas cylinders—Design, construction and testing—Part 4: Fully wrapped fibre reinforced composite gas cylinders up to 150 l with load-sharing welded metallic liners (IBR, *see* § 171.7 of this subchapter).

* * * * *

■ 47. In § 178.275, revise paragraph (i)(2)(i)(A) to read as follows:

§ 178.275 Specification for UN Portable Tanks intended for the transportation of liquid and solid hazardous materials.

* * * * *

(i) * * *

(2) * * *

(i) * * *

(A) To determine the total required capacity of the relief devices, which must be regarded as being the sum of the individual capacities of all the contributing devices, the following formula must be used:

$$Q = 12.4 \frac{FA^{0.82}}{LC} \sqrt{\frac{ZT}{M}}$$

Where:

Q = minimum required rate of discharge in cubic meters of air per second (m^3/s) at conditions: 1 bar and 0 °C (273 °K);

F = for uninsulated shells: 1; for insulated shells: U(649 − t)/13.6 but in no case, is less than 0.25

Where:

U = heat transfer coefficient of the insulation, in $kW\,m^{-2}K^{-1}$, at 38 °C (100 °F); and t = actual temperature of the hazardous material during filling (in °C) or when this temperature is unknown, let t = 15 °C (59 °F). The value of F given in this

paragraph (i)(2)(i)(A) for insulated shells may only be used if the insulation is in conformance with paragraph (i)(2)(iv) of this section;

A = total external surface area of shell in square meters;

Z = the gas compressibility factor in the accumulating condition (when this factor is unknown, let Z equal 1.0);

T = absolute temperature in Kelvin (°C + 273) above the pressure relief devices in the accumulating condition;

L = the latent heat of vaporization of the liquid, in kJ/kg, in the accumulating condition;

M = molecular weight of the hazardous material.

* * * * *

■ 48. In § 178.505, redesignate paragraphs (b)(6) and (7) as paragraphs (b)(7) and (8), respectively, and add new paragraph (b)(6) to read as follows:

§ 178.505 Standards for aluminum drums.

* * * * *

(b) * * *

(6) If materials used for body, heads, closures, and fittings are not compatible with the contents to be transported, suitable internal protective coatings or treatments must be applied. These coatings or treatments must retain their protective properties under normal conditions of transport.

* * * * *

■ 49. In § 178.506, redesignate paragraphs (b)(6) and (7) as paragraphs (b)(7) and (8), respectively, and add new paragraph (b)(6) to read as follows:

§ 178.506 Standards for metal drums other than steel or aluminum.

* * * * *

(b) * * *

(6) If materials used for body, heads, closures, and fittings are not compatible with the contents to be transported, suitable internal protective coatings or treatments must be applied. These coatings or treatments must retain their protective properties under normal conditions of transport.

* * * * *

■ 50. In § 178.609, revise paragraph (g) to read as follows:

§ 178.609 Test requirements for packagings for infectious substances.

* * * * *

(g) Where packaging is intended to contain dry ice, an additional drop test to that specified in paragraph (d), and when appropriate, paragraph (e) or (f) of this section must be performed on one sample in one of the orientations described in paragraph (d)(1) or (2) of this section, as appropriate, which is most likely to result in failure of the packaging. The sample must be stored so that all the dry ice dissipates prior to being subjected to the drop test.

* * * * *

■ 51. In § 178.703, revise paragraphs (b)(6) introductory text and (b)(7)(iv) to read as follows:

§ 178.703 Marking of IBCs.

* * * * *

(b) * * *

(6) For each composite IBC, the inner receptacle must be marked with at least the following information as required by paragraphs (b)(6)(i) and (ii) of this section. Additionally, the marking must be visible while inside of the outer receptacle. If the marking is not visible from the outer receptacle, the marking must be duplicated on the outer receptacle and include an indication that the marking applies to the inner receptacle.

* * * * *

(7) * * *

(iv) For IBCs designed for stacking, the maximum permitted stacking load applicable when the IBC is in transportation must be displayed with the symbol. The mass in kilograms (kg) marked above the symbol must not exceed the load imposed during the design test, as indicated by the marking in paragraph (a)(1)(vii) of this section, divided by 1.8. The letters and numbers indicating the mass must be at least 12 mm (0.48 inches).

■ 52. In § 178.705, revise paragraphs (c)(1)(iv) introductory text and (c)(1)(iv)(A) to read as follows:

§ 178.705 Standards for metal IBCs.

* * * * *

(c) * * *

(1) * * *

(iv) *Minimum wall thickness.* For metal IBCs with a capacity of more than 1500 liters, the minimum wall thickness must be determined as follows:

(A) For a reference steel having a product of Rm × Ao = 10,000, where Ao is the minimum elongation (as a percentage) of the reference steel to be used on fracture under tensile stress (Rm × Ao = 10,000 × 145; if tensile strength is in U.S. Standard units of pounds per square inch), the wall thickness must not be less than:

TABLE 1 TO PARAGRAPH (c)(1)(iv)(A)—WALL THICKNESS (T) IN mm, CAPACITY (C) IN LITERS

Types 11A, 11B, 11N		Types 21A, 21B, 21N, 31A, 31B, 31N	
Unprotected	Protected	Unprotected	Protected
T = C/2000 + 1.5	T = C/2000 + 1.0	T = C/1000 + 1.0	T = C/2000 + 1.5

* * * * *

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

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

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 54. In § 180.207, revise paragraph (d)(3) and add paragraph (d)(7) to read as follows:

§ 180.207 Requirements for requalification of UN pressure receptacles.

* * * * *

(d) * * *

(3) Dissolved acetylene UN cylinders: Each dissolved acetylene cylinder must be requalified in accordance with ISO 10462:2013(E) (IBR, *see* § 171.7 of this subchapter). A cylinder previously requalified in accordance with the second edition of ISO 10462(E) up until December 31, 2018, may continue to be used until the next required requalification. The porous mass and the shell must be requalified no sooner than 3 years, 6 months, from the date of manufacture. Thereafter, subsequent requalifications of the porous mass and shell must be performed at least once every ten years.

* * * * *

(7) UN cylinder bundles: UN cylinder bundles containing compressed, liquefied, and dissolved gas must be inspected and tested in accordance with ISO 20475:2018(E) (IBR, *see* § 171.7 of this subchapter).

Issued in Washington, DC, on July 14, 2022, under authority delegated in 49 CFR 1.97.

Tristan H. Brown,

Deputy Administrator, Pipeline and Hazardous Materials Safety Administration.

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